

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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CITY OF STERLING HEIGHTS POLICE &	:	Civil Action No. 1:20-cv-10041-PKC
FIRE RETIREMENT SYSTEM, Individually	:	
and on Behalf of All Others Similarly Situated,	:	<u>CLASS ACTION</u>
	:	
Plaintiff,	:	
	:	
vs.	:	
	:	<u>DEMAND FOR JURY TRIAL</u>
RECKITT BENCKISER GROUP PLC,	:	
RAKESH KAPOOR, ADRIAN HENNAH,	:	
SHAUN THAXTER and ADRIAN	:	
BELLAMY,	:	
	:	
Defendants.	:	
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THIRD AMENDED COMPLAINT

TABLE OF CONTENTS

	Page
NATURE OF THE ACTION	1
JURISDICTION AND VENUE	9
THE PARTIES.....	10
ADDITIONAL KEY NON-PARTIES	16
SECURITIES AT ISSUE	17
A. Reckitt Ordinary Shares.....	17
B. Reckitt ADSs	17
SUBSTANTIVE ALLEGATIONS	23
A. Generic Drugs and Substitution	23
B. Background on Reckitt and Suboxone.....	25
C. Reckitt Developed Suboxone Film to Thwart Competition from Generic Alternatives to Suboxone Tablets	27
D. Defendants Knew that Suboxone Film Was Not Safer than Suboxone Tablets, and Could Even Be More Dangerous.....	36
E. Defendants Misled Healthcare Providers Regarding the Safety of Suboxone Film	40
F. Defendants Engaged in a Fraudulent Scheme to Delay the FDA’s Approval of Generic Versions of Suboxone Tablet.....	44
G. Defendants Misled Medicaid Administrators Concerning the Safety of Suboxone Film	51
H. Defendants Marketed Suboxone Film to Doctors Whom They Knew Were Illegally Prescribing It in Order to Switch Patients to Film Prior to Introduction of Generic Tablets	61
I. Defendants Promoted Suboxone Film Using False and Misleading Marketing Materials.....	64
J. Suboxone Film Was Exceptionally Lucrative to Reckitt.....	65

	Page
K. Reckitt Demerged RBP to Rid Itself of Suboxone Liabilities	67
DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS MADE DURING THE CLASS PERIOD	68
A. The July 28, 2014 Press Release and Conference Call	68
B. The October 21, 2014 Press Release and Conference Call.....	80
C. The November 17, 2014 Demerger Release	83
D. The February 11, 2015 Press Release and Conference Call	84
E. The 2014 Annual Report Released on March 19, 2015	85
THE TRUTH BEGINS TO EMERGE	90
A. Reckitt Stuns Investors by Reporting Hundreds of Millions in Charges in Connection with Suboxone and the DOJ Investigation.....	90
B. The DOJ's Criminal Indictment of the Former RBP	91
C. After the Class Period, Reckitt and RBP/Indivior Settle Claims with the DOJ and the FTC, and Thaxter, Baxter, and Indivior Solutions Plead Guilty to Federal Crimes.....	91
D. Reckitt Seeks Indemnification from Indivior for \$1.4 Billion.....	96
DEFENDANTS VIOLATED ITEM 303 BY FAILING TO DISCLOSE THAT THE FRAUDULENT SUBOXONE SCHEME SUBJECTED RECKITT TO MONETARY RISKS.....	97
ADDITIONAL SCIENTER ALLEGATIONS.....	99
LOSS CAUSATION/ECONOMIC LOSS	103
APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD-ON-THE-MARKET DOCTRINE	104
NO SAFE HARBOR	107
CLASS ACTION ALLEGATIONS	107

	Page
COUNT I	108
For Violations of §10(b) of the Exchange Act and Rule 10b-5 Against All Defendants on Behalf of ADS Purchasers	108
COUNT II	109
For Violations of §20(a) of the Exchange Act Against the Individual Defendants on Behalf of ADS Purchasers	109
COUNT III.....	110
For Violations of English Common Law Fraudulent Misrepresentation and Deceit Against All Defendants on Behalf of Reckitt Ordinary Share Purchasers	110
COUNT IV.....	112
For Violations of the Financial Services and Markets Act of the United Kingdom Against Reckitt on Behalf of Reckitt Ordinary Share Purchasers	112
COUNT V	114
For Violations of English Common Law, Negligent Misrepresentation and Misstatement Against All Defendants on Behalf of Reckitt Ordinary Share Purchasers	114
PRAYER FOR RELIEF	115
JURY DEMAND	116

Lead Plaintiff City of Birmingham Retirement and Relief System (“Birmingham”) and plaintiffs City of Pontiac General Employees’ Retirement System (“Pontiac”) and City of Sterling Heights Police & Fire Retirement System (“Sterling Heights,” collectively, “Plaintiffs”) allege the following based upon the investigation of Plaintiffs’ counsel, which included a review of regulatory filings and reports by Reckitt Benckiser Group plc (“Reckitt,” “RB,” or the “Company”), securities analysts’ reports, media reports, press releases and other public statements issued by Reckitt, filings in governmental proceedings, including the actions styled *United States v. Indivior Inc.*, No. 1:19-cr-00016 (W.D. Va.), *United States v. Shaun Thaxter*, No. 1:20-cr-00024 (W.D. Va.), *United States v. Indivior Solutions, Inc.*, No. 1:20-cr-00027 (W.D. Va.), *United States v. Timothy Baxter*, No. 1:20-cr-00032 (W.D. Va.), *Federal Trade Commission v. Reckitt Benckiser Group PLC*, No. 1:19-cv-00028 (W.D. Va.), and *Federal Trade Commission v. Indivior Inc.*, No. 1:20-cv-00036 (W.D. Va.), and other publicly available information. Plaintiffs believe that, after a reasonable opportunity for discovery, substantial additional evidentiary support will exist for the allegations set forth herein.

NATURE OF THE ACTION

1. This is a securities class action on behalf of a class consisting of all persons, other than the defendants (“Defendants,” as defined herein) and those affiliated with Defendants, who purchased: (i) Reckitt American Depositary Shares (“ADSs”) on the Over-the-Counter (“OTC”) Market in the United States and/or incurred irrevocable liability for the ADSs in the United States and/or to whom title to the ADSs passed in the United States, from July 28, 2014 through April 9, 2019 (the “Class Period”), seeking to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) (collectively, the “Exchange Act claims”), and Rule 10b-5 promulgated thereunder, against Defendants; and/or (ii) Reckitt ordinary shares

on the London Stock Exchange during the Class Period, seeking to pursue remedies under English common law (the tort of fraudulent misrepresentation/deceit and the tort of negligent misrepresentation/misstatement) and Section 90A of the U.K. Financial Services and Markets Act 2000 (“FSMA”) (collectively, the “English Law claims”) against Defendants (the “Class,” as defined further below).¹

2. Opioid addiction and abuse is a raging public health crisis in the United States. As the manufacturer of Suboxone Sublingual Tablet (“Suboxone Tablet,” “Tablet,” or “Tablets”), a drug that is meant to help opioid-addicted individuals overcome their addiction, Reckitt was poised to ease this crisis. Defendants, however, lied to increase profits by devising a scheme that sought to fraudulently deny patients a lower-cost generic alternative in order to maintain its lucrative monopoly on the branded drug and deceive the market about the drug’s profitability.

3. Reckitt investors were defrauded by Defendants’ false and misleading statements and omissions concerning the supposed advantages of Suboxone Sublingual Film (“Suboxone Film” or “Film”), Reckitt’s new, reformulated Suboxone drug, over Tablets. As explained herein, Defendants knew that Film actually had a *greater* potential for harm than Tablets. But Defendants falsely told investors otherwise.

4. As a result of Defendants’ scheme, Reckitt’s former wholly owned subsidiary Indivior (formerly known as Reckitt Benckiser Pharmaceuticals Inc. (“RBP”) and referred to herein as RBP, Indivior, or RBP/Indivior, interchangeably) was indicted in April 2019 by the U.S. Department of Justice (“DOJ”). In July 2019, Reckitt paid \$1.4 billion to resolve its own

¹ Reckitt ADSs and ordinary shares are collectively referred to as “Reckitt Securities.”

potential criminal and civil liability. A year later, Indivior paid \$600 million to resolve its potential criminal and civil liability.

5. By 2009, Suboxone annual sales had grown to more than \$700 million. Suboxone Tablets, however, would lose all exclusivity that same year, making them subject to generic competition. Reckitt predicted that it would lose 80% of that revenue to generic competitor drugs. So Defendants devised a scheme to prevent that from happening.

6. The one quality of Film that was materially different from Tablets, and which was critical to Reckitt's suppression of generic competition, was the dosage form: the Film consisted of a thin strip placed under the tongue, whereas the Tablet was a conventional tablet also placed under the tongue. Defendants knew that, due to the different dosage forms, pharmacists could not legally substitute the less-expensive, generic Suboxone Tablets when presented with a prescription for Suboxone Film. Defendants could only exploit this distinction if they were able to convince physicians to switch patients to Suboxone Film. As alleged herein, Defendants used coercive and fraudulent tactics to effectuate this market switch in order to protect Reckitt's prescription base from generic competition.

7. To justify the switch from Tablets to Film, Defendants deceived investors, physicians, patients, and healthcare-benefit programs into believing that Film was safer and less susceptible to accidental child exposure (*i.e.*, children taking Suboxone by accident) and diversion (*e.g.*, illegal selling, sharing, and smuggling of Suboxone) than Tablets. But Defendants knew that Suboxone Film was not safer and less susceptible to diversion and misuse than Suboxone Tablets ***because the U.S. Food and Drug Administration ("FDA") expressly told them so.***

8. On October 5, 2009, RBP sent a letter to the FDA asking whether the FDA agreed that Suboxone Film's packaging would protect against accidental child exposure and diversion.

The FDA did not immediately respond. In the meantime, according to the Indictment, RBP executives and others internally discussed that the FDA could disagree because it was not clear how physicians would use the serial numbers on Suboxone Film packages to deter diversion, and “there is an incremental risk of the film since once a child ingests the film it will be nearly impossible to remove vs. tablets.”

9. RBP’s concern was justified. On March 29, 2010, the FDA responded to Defendants that it did not agree that Film was safer than Tablets, and was actually *more* dangerous in certain ways.

10. Meanwhile, between October 5, 2009, when Reckitt submitted the letter to the FDA, and March 29, 2010, when Reckitt received an adverse response, Reckitt’s Chief Executive Officer (“CEO”) sold 4.2 million shares of Reckitt stock for proceeds of \$204 million and Reckitt’s Chief Financial Officer (“CFO”) sold 353,000 shares of Reckitt stock for proceeds of \$17.4 million.

11. Yet Defendants falsely told investors and Reckitt’s stakeholders that Film was safer for children and less subject to diversion than Tablets in the hopes of maintaining its lucrative Suboxone franchise.

12. Relatedly, to further increase prescriptions of Film before Reckitt’s exclusivity on Tablets ran out, Defendants engineered a plan to coerce patients and physicians to switch from Tablets to Film under false pretenses. As part of this scheme, Defendants announced a “discontinuance” of the Tablet form of Suboxone based on supposed “concerns regarding pediatric exposure” to Tablets. The Tablets that Defendants had marketed for years as safe and effective suddenly became so dangerous that they had to be taken off the market and patients had to start using Film. And the danger only applied to the U.S. market: Reckitt continued to sell Tablets in

its foreign markets. The only reason for the discontinuance, of course, was to delay the FDA's approval of generic tablet forms of the drug. Defendants, however, falsely told investors that the success of Suboxone Film was due to patients, physicians, and payers (*i.e.*, Medicare and Medicaid) preferring Suboxone Film over Tablets, rather than Defendants' coercive and deceptive conduct.

13. Defendants also misled investors and the public in an attempt to game the drug-approval process to delay generic competition for the lucrative Suboxone franchise. Within days of withdrawing Tablets from the U.S. market, Reckitt filed a sham citizen petition with the FDA claiming its own Tablets were so unsafe as to require a voluntary withdrawal from the U.S. Defendants knew that by filing a citizen petition, the FDA would be required to take at least another five months to consider its merits (or the lack thereof), thereby further delaying entrance of generic Suboxone Tablets into the market and giving Reckitt more time to convert patients and physicians from Tablets to Film. The five-month delay resulted in more than \$600 million in Film sales for Reckitt.

14. Defendants' multifaceted scheme was highly successful, blocking lower-cost generic competition to Tablets and causing patients to pay more for the reformulated Film. Defendants fraudulently converted thousands of opioid-addicted patients over to Film and caused state Medicaid programs to expand and maintain coverage of Film, instead of much less-expensive Tablets, at a substantial cost to the government. Between 2010 and 2014, Reckitt received approximately \$3 billion in revenues from sales of Film.

15. Despite the apparent success of Defendants' scheme, the federal and state governments began to investigate Reckitt. In 2011, RBP received a subpoena from the U.S. Attorney for the District of New Jersey relating to the promotion, marketing, and sale of Suboxone

Film. In late 2012, the U.S. Federal Trade Commission (“FTC”) and the Attorney General of New York commenced non-public investigations of Reckitt, RBP, and other Reckitt entities concerning Film. In December 2013, the U.S. Attorney for the Western District of Virginia executed a search warrant on RBP’s headquarters in Richmond and conducted searches of the homes of four field-based employees.

16. Seeing the potential for massive liability on the horizon, in July 2014, Reckitt announced its plans to cut ties with RBP and demerge RBP from Reckitt. Reckitt omitted key information about its potential exposure and provided an illusory rationale for the demerger, stating that it wanted to focus on its health and hygiene products. In reality, Reckitt knew RBP was a ticking time bomb and wanted to rid its books of RBP. Indeed, as part of the demerger agreement, RBP agreed to indemnify Reckitt for any losses suffered or arising from liabilities associated with RBP’s business, including Suboxone.

17. After demerging RBP, Reckitt and its executives continued to conceal the truth from investors. Reckitt and its executives believed that the potential liabilities associated with Suboxone were no longer their concern.

18. Defendants were wrong. On April 9, 2019, a federal grand jury indicted Indivior PLC and Indivior Inc. on charges of healthcare fraud, wire fraud, mail fraud, and conspiracy, in connection with the marketing and promotion practices, pediatric safety claims, and overprescribing of the Film and/or the Tablet by certain physicians. The Indictment,² attached as Exhibit A, exposed Defendants’ Suboxone scheme, citing internal emails and documents

² A Superseding Indictment was filed on August 14, 2019, and was substantially similar to the Indictment.

demonstrating actual knowledge of the scheme by multiple Reckitt CEOs and CFOs and RBP's CEO, many of whom are named as defendants herein.

19. According to the Indictment, in 2012, Reckitt's investor-relations director emailed Reckitt's CEO Rakesh Kapoor and RBP's CEO Shaun Thaxter (both defendants) and others, referencing *"our plans" to withdraw Suboxone Tablet's FDA approval in order to delay FDA approval of generic versions of Suboxone Tablet.*³ Reckitt's General Counsel responded to them and other Reckitt and RBP senior executives, stating, *"please do not create any emails or other documents suggesting that we would consider" attempting to delay FDA approval of generic versions of Suboxone Tablet in this way, and "any decision we make will be based on consumer safety."* The Indictment, however, quotes an RBP manager as stating, in May 2012, to Timothy Baxter, RBP's then-Global Medical Director, and other individuals whose names are redacted, *"Under no circumstances can we make the claim that Suboxone Film is safer or better at reducing pediatric exposures than Suboxone Tablet."* The same RBP manager separately stated, *"Saying Suboxone Film is safer than any tablet on the market because Film has less ability to be snorted/injected [is an] unsubstantiated superiority claim."* The Indictment also details how Kapoor and Thaxter approved the submission of the citizen petition to the FDA even though it had been secretly altered to delete the statement that *"any results related to the original packaging should be interpreted with considerable caution."*

20. A cascade of massive settlements with the government and criminal guilty pleas followed. On July 11, 2019, the DOJ announced that Reckitt had agreed to pay \$1.4 billion to resolve its potential criminal and civil liability related to the federal investigation of Suboxone.

³ Emphasis has been added unless otherwise noted.

The resolution – the largest recovery by the United States in a case concerning an opioid drug at that time – included the forfeiture of proceeds totaling \$647 million, civil settlements with the federal government and the states totaling \$700 million, and an administrative resolution with the FTC for \$50 million. On the same day, the FTC filed a complaint, attached as Exhibit B, against Reckitt for anticompetitive practices that coerced a majority of patients to switch to the more expensive Film before the entry of lower-cost generic Tablets.

21. On June 30, 2020, Defendant Shaun Thaxter pleaded guilty to a one-count Information for his role in causing the introduction into interstate commerce of misbranded shipments of the Film, a violation of the Federal Food, Drug, and Cosmetic Act. The Information charged that Thaxter failed to prevent and correct the distribution of false and misleading pediatric exposure data to the Massachusetts Medicaid program in 2011 and 2012, prior to the start of the Class Period and the demerger of RBP and Reckitt. Thaxter resigned as CEO and Director of Indivior, and on October 22, 2020, he was sentenced to six months in federal prison, one year of supervised release, and ordered to pay a fine of \$100,000 and forfeit \$500,000.

22. In July 2020, RBP/Indivior agreed to pay \$600 million to resolve criminal and civil liability associated with the marketing of Suboxone. Indivior Inc.'s subsidiary, Indivior Solutions (formerly a division of RBP known as Reckitt Benckiser Pharmaceuticals Solutions, Inc.), pleaded guilty to the felony charge of willfully making materially false statements in connection with the delivery of and payment for healthcare benefits, items, and services in violation of 18 U.S.C. §1035.

23. On December 17, 2020, Baxter, the former Global Medical Director of RBP and former Chief Medical Officer of Indivior, pleaded guilty to the same charge as Thaxter, laid out in

a nearly identical Information, and was sentenced to six months of home detention, 100 hours of community service, and a \$100,000 criminal fine.

24. In all, the total government resolutions related to the marketing of Suboxone amounted to more than \$2 billion.

25. In response to this and other partial disclosures of the truth to investors, Reckitt's stock declined significantly. As a result of Defendants' wrongful acts and omissions, Plaintiffs and other Class members have suffered substantial losses and damages.

JURISDICTION AND VENUE

26. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§1331, 1332, and 1367, and Section 27 of the Exchange Act.

27. Certain of the claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act [15 U.S.C. §§78j(b) and 78t(a)] and SEC Rule 10b-5 [17 C.F.R. §240.10b-5] promulgated thereunder. Jurisdiction over the Exchange Act claims is conferred by Section 27 of the Exchange Act, 15 U.S.C. §78aa.

28. With respect to the English Law claims, this Court has diversity jurisdiction pursuant to 28 U.S.C. §1332. Plaintiffs Birmingham, Sterling Heights, and Pontiac are citizens of the United States. Defendants Reckitt, Kapoor, Hennah, and Bellamy are citizens of the United Kingdom; defendant Thaxter is a citizen of the United States. The amount in controversy under the English Law claims exceeds \$5 million. On information and belief, Reckitt Securities are not "covered securities" within the meaning of 28 U.S.C. §1332(d).

29. The English Law claims are so related to the Exchange Act claims such that they form part of the same case or controversy. Jurisdiction over the English Law claims is therefore also conferred by 28 U.S.C. §1367.

30. Venue is proper in this District pursuant to 28 U.S.C. §1391(b). Defendants are subject to personal jurisdiction in this District. This venue is proper pursuant to a forum selection clause in Reckitt's American Depositary Receipt deposit agreement. On November 30, 2020, U.S. District Judge Brian R. Martinotti granted Defendants' motion to transfer this action to this District pursuant to 28 U.S.C. §1404(a).

31. In connection with the acts and omissions alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce.

THE PARTIES

32. Plaintiff Sterling Heights is a pension fund that provides pension benefits to the City of Sterling Heights, Michigan police officers and firefighters and their beneficiaries. During the Class Period, Sterling Heights purchased Reckitt ADSs on the OTC Market in the United States and/or incurred irrevocable liability for the ADSs in the United States and/or title to the ADSs passed to it in the United States, and was injured thereby, as set forth in its certification previously filed with the Court and incorporated herein by reference.

33. The Reckitt ADSs reflecting Sterling Heights' purchase and its beneficial ownership of the underlying Reckitt ordinary shares were issued by Reckitt's depository bank JPMorgan Chase Bank, N.A. ("JPMorgan"), located in New York City, within the United States.

34. Sterling Heights incurred irrevocable liability in the United States to purchase the Reckitt ADSs it acquired during the Class Period. The placement of the buy order, the payment of the purchase price, transfer of the title to the securities, and other related transactions took place within the territorial jurisdiction of the United States, as follows:

(a) Sterling Heights' purchase of Reckitt ADSs was directed by its outside investment manager, WCM Investment Management ("WCM"), located in California;

(b) WCM placed the buy order through Sterling Heights' custodian Morgan Stanley, located in New York;

(c) WCM and/or Morgan Stanley purchased Reckitt ADSs for Sterling Heights on the OTC Market using the OTC Pink trading platform. OTC Pink is run by OTC Link, which is based in New York;

(i) OTC Link is an electronic inter-dealer quotation and trading system developed by OTC Markets Group. OTC Link is also an alternative trading system ("ATS") registered with the SEC. OTC Link allows broker-dealers to post and disseminate their quotes and to negotiate trades through the system's electronic messaging capability. All broker-dealers that trade on OTC Pink, OTCQX, and OTCQB have to be members of the Financial Industry Regulatory Authority ("FINRA"), must register with the SEC, and are subject to state securities regulations, providing protection from certain unethical broker-dealer practices through SEC and FINRA rules. OTC Markets Group is headquartered in New York. OTC Link LLC is also headquartered in New York. Subscribing broker-dealers can view and publish quotes and negotiate trades on all three tiers on OTC Link ATS, an inter-dealer quotation and trade messaging system. Broker-dealers access OTC Link ATS through the OTC Dealer user interface or by using OTC FIX protocol. OTC Dealer can connect to OTC Market Group's servers via public internet or through extranet, which is recommended due to the high volume of traffic. The Group's extranet providers are BT Radianz, TNS, Century Link, NYSE Technologies Connectivity Inc. (SFTI), and Options-IT, which are all headquartered in the United States. OTC Group also states that it distributes data feeds using two multicast broadcast channels, and that an "A" channel is published from their primary data center in Carlstadt, New Jersey, and a "B" channel is published from their secondary data center in Philadelphia, Pennsylvania.

(d) On information and belief based on the facts about the OTC Market alleged below, the purchase order and trade confirmation were routed through OTC Link's servers, which are located wholly within the United States;

(e) The Reckitt ADSs reflecting Sterling Heights' purchase and its ownership interest in the underlying Reckitt ordinary shares were issued by JPMorgan from its depository bank office in New York; and

(f) As required by the Deposit Agreement filed with the SEC by Reckitt, a transfer of title establishing Sterling Heights' beneficial ownership of Reckitt ADSs and the Reckitt shares on deposit on its behalf was recorded on the transfer books of JPMorgan maintained in New York.

35. Plaintiff Birmingham is a public pension fund that was organized for the benefit of current and retired public employees of the City of Birmingham, Alabama. During the Class Period, Birmingham purchased Reckitt ADSs on the OTC Market in the United States and/or incurred irrevocable liability for the ADSs in the United States and/or title to the ADSs passed to it in the United States, and was injured thereby, as set forth in its certification previously filed with the Court and incorporated herein by reference.

36. The Reckitt ADSs reflecting Birmingham's purchase and its beneficial ownership of the underlying Reckitt ordinary shares were issued by Reckitt's depository bank JPMorgan Chase Bank, N.A. ("JPMorgan"), located in New York City, within the United States.

37. Title passed to Birmingham in the United States and/or Birmingham incurred irrevocable liability in the United States to purchase the Reckitt ADSs it acquired during the Class Period. The payment of the purchase price, transfer of the title to the securities, and other related transactions took place within the territorial jurisdiction of the United States, as follows:

(a) Birmingham's purchase of Reckitt ADSs was directed by its outside investment manager, Thornburg Investment Management, Inc. ("Thornburg"), located in New Mexico, within the United States;

(b) Thornburg purchased blocks of Reckitt ordinary shares on the London Stock Exchange in its own name;

(c) Executing brokers (including Merrill Lynch, Pierce, Fenner & Smith Incorporated, J.P. Morgan Securities Inc., HSBC Brokerage Inc., Credit Suisse First Boston LLC, and Deutsche Bank Securities Inc.), acting on behalf of Thornburg, delivered Reckitt ordinary shares to Reckitt's depositary bank;

(d) The depositary bank gave ADSs to the same executing brokers;

(e) The executing brokers performed a U.S. settlement, pursuant to Birmingham's investment agreement with Thornburg, using standard U.S. settlement procedures;

(f) On settlement, Birmingham paid funds to the executing brokers for the ADSs; then those ADSs were delivered to Birmingham's account and Birmingham was entitled to Reckitt ADSs sitting in the depositary bank in the United States; and

(g) Title passed to Birmingham at the time of settlement in the United States.

38. Plaintiff Pontiac is a defined benefit municipal retirement plan that provides benefits to current and retired public employees of the City of Pontiac, Michigan. Pontiac purchased Reckitt ordinary shares during the Class Period and was injured thereby, as set forth in its certification filed herewith as Exhibit C.

39. Defendant Reckitt is a consumer goods and health conglomerate headquartered in the United Kingdom. The Company maintains substantial operations in the United States, including its corporate offices located in Parsippany, New Jersey. RBP/Indivior, which markets

and distributes Suboxone, is headquartered in Richmond, Virginia. On information and belief, Reckitt is the entity referred to in the Indictment as “Company A.”

40. Defendant Rakesh Kapoor (“Kapoor”) served as CEO and a director of Reckitt from September 2011 until September 2019. He joined Reckitt in 1987 and served in various regional and central marketing roles. Kapoor was appointed Executive Vice President – Category Development in 2006 with responsibility for global category management, research and development, media, market research, and strategic alliances. He has been called one of the highest-paid executives in the United Kingdom, receiving £25.5 million (\$32 million) in compensation in 2015 and total compensation between 2011 and 2018 of £101 million (\$126 million).

41. Defendant Adrian Hennah (“Hennah”) joined Reckitt in January 2013 and served as CFO of Reckitt from February 2013 until October 2020. Hennah was approved as a non-executive Director of Indivior PLC in November 2014, prior to the demerger of RBP from Reckitt. Hennah stepped down from the Indivior Board in May 2016.

42. Defendant Shaun Thaxter (“Thaxter”) joined Reckitt in 1995. He spearheaded the growth and development of RBP since launching the Suboxone business in 2003. Thaxter was RBP’s President from 2005 to 2009, and became RBP’s CEO in 2009. Thaxter served as the CEO of RBP both before and after its separation from Reckitt, including during the entirety of the Class Period. After the demerger, Thaxter became the CEO of Indivior. Indivior announced Thaxter’s resignation as CEO and Director of Indivior on June 29, 2020, the day before his plea agreement with the DOJ became public. On information and belief, Thaxter is a citizen and/or domiciliary of the United States based on, *inter alia*, the following facts: (i) he was CEO of a company whose principal executive offices are located in Virginia; (ii) he owns, and pays taxes on, multiple homes

in Virginia; (iii) he holds a Virginia-issued driver's license; (iv) he holds a Virginia-issued student pilot license; (v) he holds a Virginia-issued hunting license; and (vi) his wife and son reside in the United States.

43. Defendant Adrian Bellamy ("Bellamy") served as the Chairman of the Board of Directors (the "Board") of Reckitt from 2003 until May 2018. He was appointed a Non-Executive Director of Reckitt in 1999.

44. The defendants referenced above in ¶¶39-43 are also referred to herein as the "Individual Defendants," and are liable for Reckitt's fraud under Sections 10(b) and 20(a) of the Exchange Act, Section 90A of the FSMA, and English common law. Reckitt and the Individual Defendants are referred to collectively as "Defendants."

45. During the Class Period, the Individual Defendants, as senior executive officers and/or directors of Reckitt, were privy to confidential, proprietary information concerning Reckitt, its finances, operations, financial condition, present and future business prospects, and pharmaceutical products, including Suboxone, via internal corporate documents, conversations and connections with other corporate officers and employees, and attendance at management and/or Board meetings and committees thereof and reports and other information provided to them in connection therewith. Because of their possession of such information, the Individual Defendants knew or recklessly disregarded that the adverse facts specified herein had not been disclosed to, and were being concealed from, the investing public.

46. The Individual Defendants are liable as direct participants in the wrongs complained of herein. In addition, the Individual Defendants, by reason of their status as senior executive officers and/or directors, were "controlling persons" within the meaning of Section 20(a) of the Exchange Act and had the power and influence to cause Reckitt to engage in the unlawful

conduct complained of herein. Because of their positions of control, the Individual Defendants were able to and did, directly or indirectly, control the conduct of Reckitt's business.

47. The Individual Defendants are liable as participants in a fraudulent scheme and course of conduct that operated as a fraud or deceit on purchasers of Reckitt Securities. The scheme: (a) deceived the investing public regarding Reckitt's business, operations and management and the intrinsic value of Reckitt Securities; and (b) caused Plaintiffs and members of the Class to purchase Reckitt Securities at artificially inflated prices.

ADDITIONAL KEY NON-PARTIES

48. Indivior Inc.⁴ is a Delaware corporation headquartered in Richmond, Virginia that markets and distributes prescription drugs containing buprenorphine, an opioid controlled substance, under brand names including Suboxone and Subutex. Until December 23, 2014, Indivior Inc. was a wholly owned subsidiary of Reckitt and was known as Reckitt Benckiser Pharmaceuticals Inc. or RBP. After demerging from Reckitt, RBP became a subsidiary of Indivior PLC.

49. Indivior Solutions is a Delaware corporation headquartered in Richmond, Virginia that employed marketing and sales personnel for Indivior Inc. It was formerly a division of RBP known as Reckitt Benckiser Pharmaceuticals Solutions Inc. until it became a wholly owned subsidiary of RBP in September 2013. Until December 23, 2014, it was a subsidiary of Reckitt along with RBP. After the demerger, it became a wholly owned subsidiary of Indivior Inc.

⁴ The use of the terms "Indivior" or "RBP/Indivior" herein refer to Indivior Inc., Indivior Solutions, Indivior PLC, RBP, RBP Solutions, and any other RBP or Indivior entities, both collectively and interchangeably, because Plaintiffs may lack complete knowledge on the structure, roles, and/or involvement of each entity concerning the allegations herein.

50. Indivior PLC is an English public limited company headquartered in Slough, England, United Kingdom, that owned, controlled, managed, and operated Indivior Inc. and Indivior Solutions after December 23, 2014.

51. Lambertus Johannes Hermanus “Bart” Becht (“Becht”) was CEO of Reckitt from 1995 until August 31, 2011.

52. Colin Day (“Day”) was CFO of Reckitt from 2000 until March 2011.

53. Liz Doherty (“Doherty”) was CFO of Reckitt from April 2011 until March 2013.

54. Timothy Baxter (“Baxter”) served as RBP’s Global Medical Director from 2000 until December 2014. After the demerger, Baxter served as the Chief Medical Officer of Indivior until he left the company in May 2016. As the Global Medical Director, Baxter was RBP’s top medical executive and reported directly to Thaxter. He later served on Indivior’s executive committee along with Thaxter, Cary Claiborne, and Mark Crossley.

SECURITIES AT ISSUE

55. Each of the Class members acquired beneficial ownership interest in Reckitt through the purchase of one or more of the following securities: ordinary shares and/or ADSs.

A. Reckitt Ordinary Shares

56. Reckitt’s ordinary shares are publicly traded on the London Stock Exchange under the ticker symbol “RB.”

B. Reckitt ADSs

57. Reckitt’s ADSs are publicly traded on the U.S. OTC Market under the ticker symbol “RBGLY.” Reckitt sponsors its ADSs. Five sponsored ADSs represent one ordinary share.

(i) Nature of an ADS

58. The sale of ADSs was authorized by Congress in 1927, as a way to permit American investors to diversify their portfolios by acquiring shares of foreign companies without the necessity of purchasing those shares on foreign exchanges using foreign currency. The SEC has explained that “ADRs [or American Depositary Receipts]⁵ allow U.S. investors to invest in non-U.S. companies and give non-U.S. companies easier access to the U.S. capital markets.” SEC Office of Investor Education and Advocacy, *Investor Bulletin: American Depositary Receipts* (Aug. 2012) at 1 (“SEC ADR Bulletin”).

59. Reckitt ADSs are sold in the United States pursuant to regulations adopted by the SEC, including SEC Rule 12g3-2(b), 17 C.F.R. §240.12g3-2(b).

60. The purchase of an ADS is equivalent to the purchase of the underlying foreign securities (here, ordinary shares issued by Reckitt), which are held by the depositary bank for the benefit of the purchasers of the ADS.

61. As explained by the SEC:

An ADR is a negotiable certificate that evidences an ownership interest in American Depositary Shares (“ADSs”) which, in turn, represent an interest in the shares of a non-U.S. company that have been deposited with a U.S. bank. It is similar to a stock certificate representing shares of stock. The terms ADR and ADS are often used interchangeably by market participants. ADRs trade in U.S. dollars and clear through U.S. settlement systems, allowing ADR holders to avoid having to transact in a foreign currency.

SEC ADR Bulletin at 1.

⁵ ADRs allow foreign equities to be traded on U.S. stock exchanges. An ADS is the actual U.S. dollar-denominated equity share of a foreign-based company available for purchase on an American stock exchange. In other words, the entire issuance is called an ADR, and the individual shares are referred to as ADS. For convenience, and unless the context indicates otherwise, the term ADSs is used herein to refer collectively to both ADRs and the underlying ADSs on deposit as required to support their sale.

62. Thus, ADSs, including Reckitt ADSs, are securities that represent specific shares of common stock of foreign issuers that have been deposited with a U.S. bank.

63. SEC regulations, including SEC Rule 12g3-2(b), require depositary institutions to acquire and hold shares of foreign securities in an amount equal to the number of those shares sold as ADSs in the United States, based on the ratio of foreign-to-domestic shares stated in the ADR. The underlying shares of common stock must be deposited with the depositary institution by the time the ADS transaction is cleared, thereby removing them from the market until the ADS is cancelled or sold. Thus, the number of foreign shares that can be sold as ADSs in the United States is limited by the number of shares that have been issued and authorized for sale by the foreign issuer. An ADS program has no ability to expand ownership interests in the foreign issuer beyond the limits established by that issuer.

(ii) Reckitt Sponsors Its ADSs

64. Reckitt sponsors its ADSs. ADSs may be either “sponsored” or “unsponsored.” Sponsored ADSs are established pursuant to a contract signed by the foreign issuer and the depositary bank. Unsponsored ADSs are established by one or more depositary banks by filing a Form F-6 with the SEC.

65. In the “Investors” section of its website, Reckitt describes its ADS program as follows:⁶

What’s an ADR?

American Depositary Receipts (ADRs) are dollar-denominated securities that represent the ownership of ordinary shares in a non-US company, quoted and traded in US dollars in the US securities market. An ADRs [sic] allows the purchase, holding and sale of non-US shares by US investors. Dividends are paid to investors in US dollars.

⁶ See reckitt.com/investors/your-shareholding/adr-information/ (last visited 3-24-2021).

Reckitt's ADRs are traded on the over-the-counter market (OTC) under the symbol RGGLY. g [sic] Five (5) ADRs represent one (1) ordinary Reckitt share. The table below provides details of the identification of Reckitt securities on the US marketplace and the London Stock Exchange:

Symbol	Security	Listing/Trading	CUSIP/ISIN
RBGLY	U.S. security (ADR)	OTC Pink	756255204
RB.	Ordinary share	London Stock Exchange	GB00B24CGK77

66. On its website, Reckitt further states: "J.P. Morgan Chase sponsors and administers the Reckitt ADR facility," and notes that "J.P. Morgan ADR shareholder services" can be contacted at J.P. Morgan Chase Bank, N.A.'s address at 383 Madison Avenue in New York City.

67. In the Deposit Agreement, Reckitt included a "Consent to Jurisdiction" clause requiring any litigation brought by an ADS holder to be brought in any state or federal court in New York, New York, as follows:

The Company irrevocably agrees that any legal suit, action or proceeding against the Company brought by the Depositary or any Holder, arising out of or based upon this Deposit Agreement or the transactions contemplated hereby, may be instituted in any state or federal court in New York, New York, and irrevocably waives any objection which it may now or hereafter have to the laying of venue of any such proceeding, and irrevocably submits to the non-exclusive jurisdiction of such courts in any such suit, action or proceeding. The Company also irrevocably agrees that any legal suit, action or proceeding against the Depositary brought by the Company, arising out of or based upon this Deposit Agreement or the transactions contemplated hereby, may only be instituted in a state or federal court in New York, New York. The Company has appointed Reckitt Benckiser LLC, Morris Corporate Center IV, 399 Interpace Parkway, Parsippany, New Jersey 07054-0225, as its authorized agent (the "Authorized Agent") upon which process may be served in any such action arising out of or based on this Deposit Agreement or the transactions contemplated hereby which may be instituted in any state or federal court in New York, New York by the Depositary or any Holder, and waives any other requirements of or objections to personal jurisdiction with respect thereto.

(iii) The OTC Market

68. Reckitt ADSs trade on the OTC Pink market which is part of the OTC Market. The OTC Market and the Pink market are both located in the United States, and are operated by OTC Markets Group, which is based in New York City.

69. The OTC Market is regulated by FINRA and the SEC.

70. Trades on the OTC Market are accomplished through the OTC Link Alternative Trading System (“ATS”) registered with the SEC and regulated by both the SEC and FINRA. OTC Link ATS allows broker-dealers to quote any OTC equity security eligible for quoting under SEC Rule 15c2-11, 17 C.F.R. §240.15c2-11. There are approximately 10,000 securities quoted on the OTC Link ATS. OTC Link ATS delivers trade messages electronically, allowing subscribers to execute, negotiate, or decline trade messages.

71. The SEC maintains a website containing lists of alternative trading systems, which states: “An ATS is a trading system that meets the definition of ‘exchange’ under federal securities laws but is not required to register as a national securities exchange” SEC, Alternative Trading System (“ATS”) List, <https://tinyurl.com/p3k5144> (last visited 3-24-21). By rule, the SEC has exempted ATSs from the definition of “exchange” only for the purpose of relieving ATSs from the requirement to register as a national exchange subject to Section 6 of the Exchange Act, 15 U.S.C. §78f.

72. In its 2014 annual report to investors, issued on March 4, 2015 (during the Class Period), OTC Markets Group described OTC Link as follows:

Through our OTC Link ATS, we directly link a diverse network of broker-dealers that provide liquidity and execution services for a wide spectrum of securities. We organize securities into marketplaces to better inform investors of opportunities and risks – the OTCQX Best Marketplace; the OTCQB Venture Marketplace; and the OTC Pink Open Marketplace, which incentivize companies to provide better information to create more efficient prices in their securities. Our data-driven

platform enables investors to easily trade through the broker of their choice at the best possible price, and empowers a broad range of companies to improve the quality and availability of information for their investors.

73. The OTC Link ATS permits subscribing broker-dealers to view and publish quotes and negotiate trades in Pink-listed securities, including Reckitt ADSs. OTC Link ATS is described on OTC Markets Group's website as an "electronic messaging system" where "[t]raders have direct access to send, execute, negotiate or decline trade messages with increased efficiency and speed." OTC Link ATS is operated by OTC Link LLC, located in New York City.

74. Broker-dealers access OTC Link through OTC Dealer, which OTC Markets Group describes as a "high-performance, real-time, front-end application [that] provides a consolidated quotation, trading and information system to attract and access market liquidity." The trading platform includes OTC FIX, which uses the industry standard Financial Information eXchange ("FIX") protocol for quote submission, trading, and routing of execution (drop copy) reports.

75. As of December 31, 2014, 120 broker-dealers had subscribed to OTC Link.

76. All of the broker-dealers listed in the OTC Market Group's online directory of broker dealers are located in the United States.

77. According to the company profile posted by Bloomberg, "OTC Link serves clients in the United States."

78. Trades on the OTC Market are arranged through the broker-dealers who have subscribed to OTC Link ATS. The broker-dealers may execute the trade internally or externally through market or limit orders posted on OTC Link ATS. Completed trades are reported, cleared, and settled by the broker-dealers involved in the transaction. Trades on the OTC Market are deemed complete upon the delivery of funds by the buyer and delivery of securities by the seller.

79. FINRA members are prohibited from publishing quotations in any security unless the member is prepared to purchase or sell at the price quote and under the conditions stated at the

time the offer is posted. *See* FINRA, Rule 5220 (2012) (“Rule 5220”). The OTC Market Group further describes Rule 5220 on its website as follows: “Plain speak: Broker-dealers must honor their posted quotes.”

80. Transactions in Reckitt ADSs were conducted via servers and facilities located wholly within the United States.

81. According to OTC Markets Group’s fiscal-year 2013, 2014, and 2015 annual reports, its operations during the Class Period were conducted from offices located in New York City and Washington, D.C. Those reports further state (in substantially similar language) that OTC Markets Group “also contract[ed] with SunGuard Availability Services in Carlstadt, New Jersey and Philadelphia, Pennsylvania, for computer hosting and networking services, including production, back-up and disaster recovery, as well as internet and telecommunications services.” According to OTC Markets Group’s website, brokers access OTC Dealer and OTC FIX through one of five extranet providers in the United States: BT Radianz, TNS, Century Link, NYSE Technologies Connectivity Inc. (SFTI), or Options-IT.

82. Reckitt ADSs are issued, and Reckitt ordinary shares required to support the sale of ADSs are maintained, by JPMorgan, the depositary bank, located in New York, where transfers of interests in those securities are recorded.

83. As a result of the foregoing, purchasers and sellers of Reckitt ADSs incur irrevocable liability in the United States to complete transactions executed through the OTC Link ATS.

SUBSTANTIVE ALLEGATIONS

A. Generic Drugs and Substitution

84. The Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. §301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the

“Hatch-Waxman Act”) and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. §§355(b)(2) and 355G and 35 U.S.C. §271(e), establishes procedures designed to facilitate competition from lower-priced generic drugs, while maintaining incentives for pharmaceutical companies to invest in developing new drugs.

85. A company seeking to market a new pharmaceutical product must file a New Drug Application (“NDA”) with the FDA demonstrating the safety and efficacy of the new product. These NDA-based products generally are referred to as “brand-name drugs” or “branded drugs.”

86. A company seeking to market a generic version of a branded drug may file an Abbreviated New Drug Application (“ANDA”) with the FDA and obtain approval without additional safety studies by showing that its generic product is therapeutically equivalent to the already-approved branded drug. 21 U.S.C. §355(i)(2)(A)(iv). A therapeutically equivalent generic drug is “AB-rated” to the branded drug, which means it is the same in active ingredient, dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use.

87. AB-rated generic drugs can be substituted at the pharmacy to fill a prescription for the branded product. All 50 states and the District of Columbia have drug-substitution laws that encourage and facilitate this type of substitution. When a pharmacist fills a prescription written for a branded drug, these laws allow or require the pharmacist to dispense an AB-rated generic version of the drug instead of the more expensive branded drug, unless a physician directs or the patient requests otherwise.

88. The cost-efficient means of competition for a generic product is substitution at the pharmacy. As a practical matter, if a generic cannot be substituted at the pharmacy, the economically meaningful market for the generic product disappears. Generic substitution is based,

in part, on the premise that generic products will not be promoted like branded drugs. While the generic theoretically can attempt to market a non-substitutable product directly to prescribing physicians, such a costly undertaking undermines the ability of generic companies to offer the lower prices that the federal and state regulatory framework was intended to foster. Additionally, this kind of marketing is impractical because the generic company promoting the product has no way to ensure that the pharmacist substitutes its product, rather than a competitor's.

89. The Hatch-Waxman Act and state substitution laws have succeeded in facilitating lower-cost generic competition: generic drugs typically capture over 80% of a branded drug's sales within six months of introduction into the market. Generic drug products are usually far cheaper than the branded version, with discounts often reaching 85% or more off the brand price. Thus, generic competition has generated large savings for patients, healthcare plans, and federal and state governments. The Generic Pharmaceutical Association has reported that use of generic versions of brand-name drugs saved the U.S. healthcare system \$265 billion in 2017 alone.

B. Background on Reckitt and Suboxone

90. Opioid addiction is an epidemic in the United States. From 1999 to 2017, approximately 400,000 people died from an overdose involving an opioid, including prescription and illicit opioids such as heroin and oxycodone. Prior to December 23, 2014, Reckitt maintained a pharmaceutical division, RBP, dedicated to treatment of addiction to opioids. For many years, RBP's overwhelming source of revenue was the manufacture and sale of Suboxone Tablets, a prescription pharmaceutical product approved for the treatment of opioid addiction, and the predecessor to Suboxone Film. RBP was, for all intents and purposes, a one-drug business – Reckitt described Suboxone as “by far the largest part of the Pharmaceuticals business” in 2011. Between 2010 and 2013, between 79% and 82% of RBP's revenue was attributed to Suboxone

Tablets and Film. In 2014, 72% of RBP's revenue was attributed to Suboxone Film.⁷ In 2013, Suboxone accounted for 20% of Reckitt's total profits.

91. From 2006 through 2019, **100%** of RBP/Indivior's U.S. net revenue was attributed to Suboxone, as shown in Exhibit D, attached hereto.

92. Suboxone is a combination of the opioid buprenorphine and the opioid antagonist naloxone. Buprenorphine is the only opioid approved for the treatment of opioid addiction outside of a clinic. It binds to opioid receptors and reduces withdrawal symptoms. Naloxone has no therapeutic role but instead functions as an abuse deterrent; if Suboxone is crushed and injected, the naloxone triggers immediate withdrawal symptoms. When Suboxone is taken orally, as intended, the naloxone has no effect.

93. On October 8, 2002, Reckitt, through RBP, received FDA approval of Suboxone Tablet and Subutex Tablet, the first buprenorphine-containing drugs for use in the treatment of opioid addiction and/or dependence. The Suboxone Tablet contained both buprenorphine and naloxone, which were not subject to patent protection. The Subutex Tablet was similar to the Suboxone Tablet, but it did not include naloxone. It was intended for certain patient populations, such as those hypersensitive to naloxone.

94. In 1993, RBP requested orphan-drug designation for buprenorphine under the Orphan Drug Act ("ODA"), 21 C.F.R. §316. Congress enacted the ODA in 1983 to provide incentives for the development of drugs for rare diseases or conditions that would not otherwise be developed due to the small patient population and lack of profitability of such drugs. The ODA defines a "rare disease or condition" as any disease or condition that: (A) affects less than 200,000

⁷ As described herein, Reckitt pulled Suboxone Tablets from the market in the second quarter of 2013.

persons in the U.S.; or (B) affects more than 200,000 persons in the U.S. and for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug for such disease or condition will be recovered from sales in the U.S. of such drug. In approving Suboxone, the FDA recognized orphan-drug exclusivity for Suboxone and Subutex from October 8, 2002 until October 8, 2009, based on the FDA's belief that Reckitt would not recover the cost of developing the product.

95. Reckitt, through RBP, thus received seven years of exclusivity, during which time no generic Suboxone Tablets could be approved. But since both of Suboxone's active ingredients are so-called legacy drugs, meaning they are no longer individually under patent, Reckitt was not granted the standard 20 years of exclusivity given to most new drugs.

96. Suboxone proved far more successful than the FDA anticipated. By 2009, Suboxone annual sales had grown to more than \$700 million. Suboxone Tablets, however, would lose all exclusivity that same year, making them subject to generic competition. Reckitt predicted that it would lose most of that revenue to competitor drugs, particularly generic versions of the Suboxone Tablet, after its exclusivity period due to orphan-drug status ended on October 8, 2009. Indeed, by 2010, multiple generic applicants had filed ANDAs seeking to sell generic Suboxone Tablets.

C. Reckitt Developed Suboxone Film to Thwart Competition from Generic Alternatives to Suboxone Tablets

97. Between December 2006 and March 2007, knowing that Suboxone's exclusivity would soon expire, Reckitt began developing Suboxone Film, a new buprenorphine-containing drug, which it believed would be protected by patent and could replace the Suboxone Tablet. Defendants planned to promote Suboxone Film by claiming it was safer than Suboxone Tablets, though there were no scientific studies to establish that claim.

98. The development of Suboxone Film was undeniably motivated by Defendants' concern about the impact of generic competition on its sales of Suboxone Tablets. For instance, in its annual reports issued between 2008 and 2011, Reckitt stated that "up to 80% of the revenue and profit" of the Suboxone Tablet business "might be lost in the year following the launch of generic competitors, with the possibility of further erosion thereafter." Reckitt also stated in the 2010 Annual Report, "[I]n the event of generic competition to the Suboxone Tablet, the Group expects that the Suboxone sublingual Film will help to mitigate the impact thereof." Further, according to the 2010 Annual Report, "It is well known that by far the largest part of the Pharmaceuticals business, the Suboxone Tablets in the USA, can become subject to generic competition at any time. To mitigate the potential impact of this, in August 2010 we launched a patent-protected . . . Suboxone film."

99. Suboxone Film contains the same active ingredients and is clinically interchangeable with Suboxone Tablets. Reckitt even obtained FDA approval for Suboxone Film based almost exclusively on previous studies that Reckitt used to demonstrate the safety and efficacy of Suboxone Tablets. Any differences between the two formulations are clinically insignificant.

100. The one quality of Film that was materially different from Tablets, and which was critical to Reckitt's suppression of generic competition, was the dosage form: the Film consisted of a thin strip placed under the tongue, whereas the Tablet was a conventional tablet, also placed under the tongue. Defendants knew that, due to the different dosage forms, generic Suboxone Tablets could not be considered AB-rated to Suboxone Film and, therefore, pharmacists could not legally substitute the less-expensive, generic Suboxone Tablets when presented with a prescription for Suboxone Film.

101. Defendants could only exploit this distinction if they were able to convince physicians to switch patients to Suboxone Film. As alleged herein, Defendants used coercive and fraudulent tactics to effectuate this market switch in order to protect Reckitt's prescription base from generic competition.

102. On October 20, 2008, Reckitt, through RBP, filed an NDA for Suboxone Film. As explained herein, on October 5, 2009, Reckitt sent a letter to the FDA asking whether it agreed that Suboxone Film was safer and more effective than the Tablet form. On March 29, 2010, the FDA responded that it did not agree that Suboxone Film was safer than Tablets, and is actually more dangerous than Tablets in certain ways.

103. Although the FDA did not find Film to be safer than Tablets, it nevertheless approved the NDA on August 30, 2010, and Reckitt, through RBP, launched the Film in September 2010.

104. Defendants then began a fraudulent scheme to extend Reckitt's Suboxone monopoly by making false statements about the safety of Film as compared to Tablets and coercing patients to switch to Film from Tablets. Because the generic Tablets would not be substitutable for the Film, getting patients to switch to the Film before generic Tablets were on the market would greatly mitigate the impact of generic entry. According to a 2009 report on the pharmaceutical industry by the European Commission, "it is of utmost importance for the originator company to bring the follow-on product on the market before the first product effectively loses exclusivity." Therefore, converting patients to the Film before generic Tablets entered the market became a top business imperative.

105. To coerce patients to make the switch, Reckitt fabricated a safety story that the Film's individual packaging made it safer than the Tablets because it reduced the risk of accidental

pediatric exposure. There was no data or scientific study to support that claim. Reckitt also raised the price of the Tablets, making them more expensive than the Film even though they were cheaper to make.

106. In 2006, Thaxter and others started working on a plan to replace Suboxone Tablets with a new version that could defend Reckitt's profits from generic competition. Thaxter said that the new version would offer "superior safety" as part of a "generic defence plan" that he spearheaded. Specifically, during an evaluation of Thaxter's performance in 2006, which included a self-assessment, Thaxter commented that he "[d]eveloped a generic defence plan focusing on: 'new adipate formulation to replace Suboxone on the grounds of superior safety which is currently in genotoxicity testing[.]'"

107. Between in or about December 2006 and March 2007, Reckitt, RBP, and others discussed ways to delay FDA approval of generic versions of Suboxone Tablets by discontinuing Suboxone Tablets under the pretext of a safety concern, thereby triggering FDA safety-related processes that could take as long as a year. According to the Indictment and sentencing materials, Baxter wrote, "***We could tie up generic for 1 year.*** . . . When we file for film and withdraw tablet [the FDA] is precluded from approving another tablet until they have made a determination in response to a petition from generic company to determine that product was not withdrawn for safety or efficacy"; and a "negative safety issue" could "prevent approval of generic." Reckitt and RBP personnel wrote, "***We need to think creatively about a safety story***"; "we probably also need to think very negatively about [Tablets] and identify aspects that could be unsafe"; and "***We cannot prevent generics . . . We can delay.***" Baxter also made a timeline showing how this strategy could work and how long generics could be delayed.

108. In early 2007, Thaxter, Baxter, and others spoke with attorneys and consultants regarding the need for “clinical data” to prove any superior safety of the new version of Suboxone, according to notes of and emails about those meetings. They also discussed that, if they got such clinical data, they could submit it to the FDA, to try to “prevent approval” of other companies’ generic versions of Suboxone.

109. Notes written by Baxter during a 2007 meeting illustrate how Reckitt reverse-engineered a safety issue with Suboxone Tablets without any clinical data to prevent approval of generic tablets. During Baxter’s sentencing hearing, the U.S. Attorney entered into the record Baxter’s handwritten notes dated 2/9/07, attached as Exhibit E, which state as follows:

Routes to protect [redacted]⁸ from generic:

- Negative safety issue [with] sublingual
- Superior safety/efficacy of oral film

Either of the above would prevent approval of generic sublingual.

To prove superior safety or efficacy would involve generation of clinical data.

Eg is there less abuse liability [with] film than sublingual?

No other route would prevent generic entry [with] sublingual.

Id.

110. By introducing Suboxone Film, Defendants engaged in an anticompetitive practice known as “product hopping” or “evergreening,” which occurs when a company tweaks its product slightly without any actual improvements, and then applies for a new patent with the intent of keeping its market share intact.

⁸ On information and belief, and based on the context of the notes, Baxter is referring to Suboxone.

111. The Film and the Tablet had similar active ingredients, and there were no clinically significant differences in their benefits and risks. Both drugs contained buprenorphine and naloxone, were intended to be taken by placement under the tongue until dissolved, and daily doses containing more than 24 mgs of buprenorphine were not shown to provide any clinical advantage over lower doses. The Film differed from the Tablet in that the Film had a thin form, stuck to the tongue and/or mouth, dissolved more rapidly, potentially had higher bioavailability⁹ at certain doses, was formulated to taste better, and was dispensed in individually wrapped, sealed, single-dosage foil pouches each bearing a serial number. Unlike the Film, the Tablet was dispensed, as the name suggests, in tablet form and stored in child-resistant medication bottles.

112. The Film offered no significant actual benefits for patients over the Tablet. FDA approval of the Film was based on the same efficacy studies that were used to establish the safety and efficacy of the Tablets, as well as Reckitt's representation that the Film had sufficient equivalent bioavailability to the Tablets. Indeed, Reckitt represented to the FDA that any differences between the two formulations were "clinically insignificant." The dosage strengths of the two were identical until August 2012, at which point the FDA approved higher dosage strengths of Film.

113. The Film, however, had certain *disadvantages* concerning accidental child exposure and diversion when compared to the Tablets, including: (1) the Film's rapid dissolution creates barriers to removal if accidentally ingested; (2) because patients are known to divide doses of Suboxone, the leftover Film cannot be stored safely after opening the foil pouch; (3) the Film is more likely to become stuck on the tongue if accidentally ingested by a child; (4) the Film is

⁹ Bioavailability refers to the ability of a substance or drug to be absorbed or used by the body.

more dangerous because of its less unpleasant taste compared to the Tablets, making children less likely to spit it out; (5) the Film's higher dosage strength increases dosage exposure to children; (6) the Film contains higher naloxone bioavailability, increasing the risk of opioid withdrawal symptoms when taken as intended; and (7) the Film is easier to conceal and smuggle into prisons. Due to the significant disadvantages of the Film over the Tablet, Reckitt does not market Suboxone Film anywhere in the world besides the United States – even though it is approved for sale in more than 30 countries. In fact, the real benefit of the new dosage form of Suboxone was only seen by Reckitt, not patients, physicians, or payers.

114. The Film, however, is protected by patent until 2023 and, unlike the Tablets, did not face imminent competition from generic manufacturers. But since the Film would not be AB-rated to Tablets, pharmacists could not legally substitute the less-expensive generic Tablets when they were given a prescription for Film. Thus, in order to justify the switch from Tablets to Film, Defendants fabricated the rationale that Film was safer than Tablets for children who are accidentally exposed to the drug. And Reckitt took product hopping a step further by disseminating false information to undermine the Tablet while aggressively promoting the Film.

115. Thaxter, Baxter, and others decided that RBP would move forward in developing the new, patented, dissolving film strip version of Suboxone called Suboxone Film.¹⁰ In 2008, Baxter and others sent the FDA a list of ideas for why Film could offer superior safety. Specifically, they stated that RBP was developing Film “as a means of [g]uarding against unintentional pediatric exposure” – meaning children accidentally taking drugs – by packaging

¹⁰ RBP partnered with another company to develop the new version of Suboxone as a dissolving film strip, rather than a tablet. The other company had patents that could prevent competitors from copying the dissolving film strip. On information and belief, that company is MonoSol Rx.

each film in a child-resistant foil pouch, instead of using conventional medication bottles with child-resistant caps. They further stated that Film could “protect against diversion” – meaning people selling or sharing drugs – because Film would stick to people’s mouths. However, they did not provide the FDA with scientific studies or tests showing that Film guarded against unintended pediatric exposure or protected against diversion. These were untested ideas.

116. Between in or about May 2009 and August 2010, while awaiting FDA approval of the NDA for Suboxone Film that had been filed on October 20, 2008, RBP managers drafted marketing plans for the drug. The draft plans listed “Key Success Drivers” for Suboxone Film such as “Driving physician prescriptions for Suboxone film,” “Driving formulary support for Suboxone film through payors,” and “Driving patient Suboxone film trial.” The draft plans included the messages that Suboxone Film was “a more responsible medication from a public health perspective,” was a “less divertible/abusable formulation,” and had a “lower risk of child exposure,” and that the generic drug would “jeopardize the entire disease space,” though there were no scientific studies to establish these claims. Thaxter received these marketing plans. The draft plans noted that public healthcare benefit programs such as Medicare, Medicaid, and the Veterans Administration paid for 27% of all Suboxone Tablet and Subutex Tablet prescribed, while private healthcare benefit programs paid for 55%.

117. On June 9, 2009, RBP’s medical director told fellow RBP medical personnel, “*We need to develop a story about childhood exposures to set the stage for switching patients*” to Suboxone Film.

118. On August 21, 2009, the FDA declined to approve Reckitt and RBP’s NDA for Suboxone Film because it did not contain an adequate risk evaluation and mitigation strategy (“REMS”) to address the FDA’s concerns about misuse, abuse, and accidental overdose. A REMS

is a drug-safety program that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. While all medications have labeling that informs healthcare stakeholders about medication risks, only a few medications require a REMS.

119. On October 5, 2009, Reckitt, through RBP, sent a letter to the FDA asking whether the FDA agreed that Suboxone Film's packaging would protect against diversion and accidental child exposure. The FDA did not immediately respond. According to the Indictment, RBP executives and others internally discussed that the FDA could disagree with RBP because it was not clear how physicians would use the serial numbers on Suboxone Film packages to deter diversion, and "there is an incremental risk of the film since once a child ingests the film it will be nearly impossible to remove vs. tablets." Thus, Defendants harbored concerns that the FDA would disagree with Reckitt's position.

120. Between October 5, 2009, when Reckitt submitted the letter to the FDA, and March 29, 2010, when Reckitt received a response (described below), Reckitt CEO Becht sold 4.2 million shares of Reckitt stock for proceeds of \$204 million and Reckitt CFO Day sold 353,000 shares of Reckitt stock for proceeds of \$17.4 million.

121. On November 24, 2009, RBP resubmitted its NDA for Suboxone Film to the FDA, including a REMS.

122. According to the Indictment, on January 22, 2010, Thaxter told Reckitt executives, "Our immediate focus is to get the FDA approval for [Suboxone Film] asap to switch the business ahead of the generic."

D. Defendants Knew that Suboxone Film Was Not Safer than Suboxone Tablets, and Could Even Be More Dangerous

123. On March 29, 2010, the FDA responded to RBP's October 5, 2009 letter that sought the FDA's agreement that Suboxone Film's packaging would protect against accidental child exposure and diversion. Not only did the FDA disagree that the packaging for Suboxone Film provides meaningful incremental protection against pediatric exposure to the medication, the FDA actually stated that Suboxone Film could be even *more dangerous* than Suboxone Tablets. The FDA stated, in pertinent part:

The Agency will not comment on whether the serial numbers [on Suboxone Film's packaging] would lead to a decrease in diversion of a drug product because drug diversion issues are regulated by DEA.

* * *

No, we do not agree that the packaging for [Suboxone Film] provides meaningful incremental protection against pediatric exposure. Although the foil pouches fulfill the child resistant effectiveness standards and the foil pouch bears warning statements alerting patients to keep out of reach of children, *no data were provided to support that these measures will encourage patients to store [Suboxone Film] in a manner which prevents accidental pediatric ingestion.* Because patients are known to divide tablets, *it may be expected that patients will remove films from the package and have partial doses that are neither in the child-resistant pouch nor in a child-resistant medication bottle.* Furthermore, *because the film cannot be spit out (unlike a tablet) it is possible that a child who obtains access to even one dose might be more adversely affected than a child who obtains access to a single tablet.*

124. The FDA declined to answer whether it agreed that Film protected against diversion, stating that the question was one for the U.S. Drug Enforcement Administration ("DEA"). Prosecutors did not find any evidence that RBP then asked the DEA.

125. In the three months after the FDA responded, Becht sold another 600,260 shares for proceeds of \$29 million, and Day sold another 150,000 shares for proceeds of \$7.3 million.

126. Thaxter, Baxter, and other Reckitt and RBP personnel understood from the FDA's response that they lacked substantiation to inform healthcare providers that Suboxone Film was

safer than alternative drugs such as Tablets. According to the Indictment, RBP executives and managers wrote to each other, “The FDA has stated that we have no proof that patients will not take the film out of the [pouch] and cut it into multiple doses. Thus not reducing potential exposure. . . . Even then the FDA points out that the film may not be swallowed thus making more buprenorphine available”; that the FDA’s response could “be a bigger issue as it may imply the overall risk/benefit is not favorable for our film (vs tablet)”; and, “It looks like they are trying to deny us the ability to make a claim on additional pediatric safety of the film.”¹¹ With regard to misuse, abuse, and diversion, Reckitt and RBP executives, managers, and personnel knew from the FDA’s response that Suboxone Film’s thin form potentially could make it easier to conceal, and thus more susceptible to smuggling than Tablets; its individual packaging could make it more portable, including for reselling and sharing; and the serial numbers on the pouches were not electronically tracked and not shown to deter diversion. With regard to accidental child exposure, they knew that Suboxone Film had attributes that potentially could make it more dangerous to children, including that it stuck and could not easily be spit out if accidentally taken by a child; dissolved more rapidly, leaving less time to remove it from a child’s mouth before absorption; had potentially higher bioavailability at certain doses, potentially increasing the severity of an incident; was formulated to taste better, potentially reducing the likelihood that a child would seek to remove it; and could not easily be re-secured in its original packaging, which, unlike a bottle with a child-resistant cap, was not designed to be re-closed.

¹¹ According to sentencing documents, on March 30, 2010, Baxter wrote to Thaxter and others, stating: “It looks like they are trying to deny us the ability to make a claim on additional pediatric safety of the film. ***I believe that we will need to collect data on this as a post marketing exercise before we can make any specific claim,*** although we will be able to describe the nature and intent of the packaging in marketing materials.”

127. On or about August 30, 2010, the FDA approved Suboxone Film, including the REMS and prescribing information for the drug. None of these materials approved by the FDA stated that Suboxone Film was safer than alternative drugs such as Tablets, or reduced the risk of misuse, abuse, diversion, or accidental child exposure. In the materials approving Suboxone Film, the FDA stated, in pertinent part, as follows:

The film formulation is intended by the Applicant to be similar in efficacy to Suboxone sublingual tablets, while offering additional safety and increased compliance. ***Reckitt Benckiser reports that the formulation was “created for the purpose of minimizing abuse and misuse of the product, including unintended and potentially dangerous exposure in children.”*** Other stated goals include increasing patient compliance, minimizing counterfeiting, minimizing illegal use and diversion, and decreased product damage during transport and storage compared to sublingual tablets. The achievement of these goals is based on the use of a unit dose product and package that is child-resistant, has enhanced physical integrity, and improved coding.

* * *

No new efficacy studies were included in this application. There was no statistical review of the clinical data. The efficacy data and recommendations for dosing are based on the approved application for Suboxone.

* * *

Overall, no major new safety findings concerning the combination of buprenorphine and naloxone were identified in this review.

Almost all of the safety experience with the proposed new formulation was derived from a single study. This study had a number of flaws, including inadequate training of personnel conducting safety exams, inconsistent recording of findings, treatment of participants with dosing regimens not recommended in the proposed labeling, and a high drop-out rate. ***As a result, although no major safety concerns arose in this study, the quality of the data and their relevance to the proposed labeling are questionable. . . . Because of buprenorphine’s poor oral bioavailability, tablets swallowed whole would be less harmful.*** It should be noted that ***the proposed filmstrip product cannot be spit out easily and dissolves quickly.*** Therefore, ***to the extent that some cases may be mitigated by the child spitting out the tablet before full absorption, the filmstrip product could be more hazardous than the tablet.*** However, ***the unit-dose packaging will help protect against this as long as the medication is not removed from the packaging and left out. (This may occur if patients use fractions of a strip, which is apparently common practice with tablets.)***

* * *

Reckitt Benckiser has implied that this product may represent an advantage over the current tablet products with respect to diversion. No information on accountability of drug supply for clinical trials of the tablet formulation is available, because the registration studies were done under supervised administration conditions (and in some cases used a liquid formulation). Therefore, there is no basis for comparison, but there does not appear to be any reason to conclude that this formulation rendered the study drug particularly resistant to diversion.

* * *

The film strip can be expected to be associated with systemic adverse events similar to those seen with other formulations, and, ***if anything, may be more irritating locally.***

* * *

The overall safety profile of this product is similar to that of the approved sublingual tablets.

* * *

This product represents a new formulation of an approved product, offering relatively minor advantages. The more rapid dissolution may be perceived as a convenience to patients. The unit-dose packaging is likely to be an effective deterrent to accidental pediatric exposure. Pediatric exposures to the currently-marketed tablets continue to occur, but are generally without severe medical consequences.

Although the sponsor has described plans to use sophisticated methods to protect the supply chain from diversion, reports from the post-marketing surveillance program indicate that most diverted supply is from patients who share or sell parts of their own prescriptions; therefore this effort, although commendable, may have little impact. Conversely, ***the difficult-to-counterfeit individual packages may actually increase the street value of diverted product because product identity is ensured.***

128. Thaxter promptly told Reckitt executives, including Reckitt's then-CEO Becht and then-CFO Day, "We will be making the most of every minute between now and generic approval to convert our tablet business to film," including a "Full Blitz campaign for salesforce through Thanksgiving." For the full blitz campaign, RBP salespeople planned to raise "diversion and misuse and pediatric safety" in sales presentations to physicians, even though there were no

scientific studies to establish that Suboxone Film was safer with regard to diversion, misuse, or pediatric safety.

129. Thaxter and other executives at RBP also strategically structured the bonuses and incentives for sales employees to reward only Film sales. Tellingly, Indivior's later settlement with the DOJ included the requirement that Indivior completely disband its United States Suboxone sales force and never reinstate it.

E. Defendants Misled Healthcare Providers Regarding the Safety of Suboxone Film

130. On September 2, 2010 (three days after Suboxone Film received FDA approval), Becht emailed approximately 20 RBP executives and managers, including Thaxter and RBP marketing personnel, falsely stating that Suboxone Film was "safer," and encouraging them to "convert [patients] from tablets to films, thereby protecting our Net Revenues in the USA."

131. After the launch of Film, the RBP sales force messaged to doctors and pharmacists that they should switch patients from the Tablet to the Film version of Suboxone in part to reduce unintended pediatric exposure to, and diversion of, the drug. These messages were delivered even though there were no studies or tests showing that Film guarded against unintended pediatric exposure or protected against diversion. Thaxter at the time was RBP's CEO, Film was the only product RBP was promoting, and Thaxter was generally aware that these messages were being used.

132. On September 6, 2010, an RBP national sales supervisor emailed approximately 50 RBP salespeople, encouraging them to tell physicians that Suboxone Film was "safer because of the packaging."

133. In October 2010, Thaxter accompanied an RBP salesperson to meetings with doctors in Virginia. Afterward, Thaxter commented to the salesperson that "Pediatric and D&M

[meaning pediatric exposure and diversion and misuse] are key drivers for physicians,” and one doctor was “motivated by improved safety of film.”

134. On October 17, 2010, Thaxter told RBP personnel to revise the performance appraisals and incentive programs for salespeople to reward “film sales only.” He stated that RBP salespeople without “adequate film sales” would be fired, or, as he put it, “exiting the company,” as they had “every possible resource to enable them to generate demand for a scheduled narcotic that is being given away for free to an addicted population.” Thereafter, RBP revised the performance appraisals and incentive programs to be based primarily on the percentage of Suboxone Film compared to Tablet sales in the salesperson’s territory (sometimes called the “film market share” or “film share”).

135. On October 25, 2010, RBP sales supervisors discussed baseless “dialogue points” that RBP salespeople were using to highlight Suboxone Film’s “advantages” to physicians and pharmacists, which included “Reduced misuse/diversion” and “Public safety – reduced pediatric exposure.” On November 3, 2010, an RBP sales supervisor emailed the dialogue points to Thaxter.

136. In December 2010, RBP’s vice president for clinical affairs, who reported directly to Thaxter, met with physicians in California and elsewhere, and in the presence of RBP salespeople, falsely stated to the physicians that Suboxone “Film addresses child safety and abuse and diversion” and was a “safer product.”

137. On February 14, 2011, an RBP national sales supervisor instructed a regional sales supervisor in Michigan and a sales representative in Ohio to:

not be afraid to let the physician know very clearly what you believe. If you believe that Suboxone Sublingual Film will lower pediatric exposure, or lower diversion and misuse let them know. You are the expert and because of all you have done, the relationships you have built, they will be receptive to what you believe.

138. On March 11, 2011, Becht falsely stated in Reckitt's publicly filed 2010 annual report that Suboxone Film was "better from a child safety point of view, mak[ing] it more attractive for doctors to prescribe."

139. On April 13, 2011, Thaxter falsely stated in a corporate newsletter that Suboxone Film "has the potential for greater child safety."

140. In July 2012, at a Reckitt investor presentation, in the presence of Reckitt's new CEO Kapoor,¹² Thaxter falsely stated that Suboxone Film was "less divertable and abusable."

141. Between September 2010 and December 2011, RBP sales representatives reported to their supervisors and their fellow sales representatives a list of specific statements and representations made to physicians, pharmacists, and other healthcare providers to use as models for promoting Suboxone Film to falsely induce them to prescribe and dispense Suboxone Film. *See* Indictment, Ex. A at ¶¶43-72. For example, RBP sales representatives told physicians in Michigan that Suboxone Film is the "safest choice," has "less chance of inadvertent use by kids," can "protect the community," and can "protect office-based treatment" from being banned. *Id.* at ¶46.

142. Reckitt, through RBP and its executives, employees, and agents, knew that messages like those described in ¶¶130-141 above materially influenced healthcare providers to prescribe and dispense Suboxone Film, and recommend the prescribing and dispensing of Suboxone Film. In January 2011, an RBP contractor reported to RBP executives, managers, and personnel that in a survey of 245 physicians who had prescribed Suboxone Film, 68 physicians (approximately 28%) stated that they did so because it "[d]ecreases misuse/abuse/diversion," and

¹² Kapoor became Reckitt's CEO in September 2011.

26 physicians (approximately 11%) stated that they did so for “[s]afety re: inadvertent use by children.” Additionally, the physicians rated “Ability to minimize unintentional pediatric exposure” and “Reduces the likelihood of misuse & diversion” as the second- and third-leading reasons to prefer Suboxone Film, respectively. More than 80% of the physicians, and 98% of the high-prescribing physicians stated that they learned about Suboxone Film from RBP salespeople. Thaxter received the results of the survey in January 2011.

143. Reckitt, through RBP and its executives, employees, and agents, knew that the messages described in ¶¶130-141 above, and others like them, were false and misleading. Contrary to this messaging by RBP salespeople, Reckitt and RBP did not have studies or tests to substantiate safety claims. In fact, in addition to the FDA’s March 29, 2010 letter, which informed Reckitt that it lacked substantiation to claim that Suboxone Film better protects against accidental child exposure than Suboxone Tablets, on June 30, 2011, an RBP contractor reviewing information as part of the Suboxone Film REMS told RBP that Suboxone Film was *more frequently abused* parenterally (*e.g.*, by injection) and involved in *more accidental child exposures* per million doses than Suboxone Tablet. The contractor later retracted these findings, but the issues remained complex and unresolved. For example, at a meeting in November 2012, Baxter stated, “With a tablet, [children have] options. They can spit it out. They can swallow it. With the film, not necessarily. We know, it’s stuck” in the child’s mouth.

144. Many of the RBP salespeople’s safety claims about Film were written down in “activity reports” they submitted to their superiors. RBP did not have a full-time compliance professional monitoring or reviewing these reports. On the other hand, RBP had a compliance committee that included sales supervisors. In December 2011, one of the sales supervisors on the compliance committee suggested discontinuing the activity reports (examples of which are set

forth in the Indictment, Ex. A at ¶¶43-72), because their “contents” were “compliance risks.” By February 2012, RBP’s compliance committee discontinued the reports. In other words, RBP salespeople were documenting actions that companies should not be doing. And what RBP did in response was put a stop to the writing, not the wrongdoing. Thus, the problem revealed in the reports – that salespeople were misstating or overstating the safety of Film – was not corrected.

145. In or about 2012 to 2013, RBP managers discussed that, “Under no circumstances can we make the claim that Suboxone Film is safer or better at reducing pediatric exposures,” and “Saying Suboxone Film is safer than any tablet on the market because Film has less ability to be snorted/injected [is an] unsubstantiated superiority claim.”

146. Defendants failed to disclose any of this information to the market.

F. Defendants Engaged in a Fraudulent Scheme to Delay the FDA’s Approval of Generic Versions of Suboxone Tablet

147. Between in or about 2006 and during the Class Period, Reckitt, through RBP and its executives, employees, and agents, made, and caused to be made, statements and representations that RBP was discontinuing the distribution of Suboxone Tablet due to safety concerns, when, in fact, the reason for discontinuing the distribution of Suboxone Tablet was to delay the FDA’s approval of generic versions of Suboxone Tablet.

148. On June 21, 2012, Reckitt’s investor-relations director emailed Kapoor, Thaxter, and others, referencing *“our plans” to withdraw Suboxone Tablet’s FDA approval in order to delay FDA approval of generic versions of Suboxone Tablet*. Reckitt’s general counsel responded by emailing Kapoor, Reckitt’s then-CFO Doherty, and Reckitt’s investor-relations director, as well as Thaxter and RBP’s general counsel, and others, stating, *“please do not create any emails or other documents suggesting that we would consider” attempting to delay FDA*

approval of generic versions of Suboxone Tablet in this way, and “any decision we make will be based on consumer safety.”

149. Between January 6, 2012 and September 14, 2012, Reckitt and RBP, knowing that potential competitors were preparing applications for FDA approval of generic versions of Suboxone Tablet, contracted two companies to do a study on unintended pediatric exposure. Baxter approved the project, and delegated supervision of it to an RBP Medical Affairs Manager who reported to him. In the study, the contractors looked at notes of telephone calls to poison-control centers regarding mentions of unintended pediatric exposure to buprenorphine, tried to determine which specific drug was implicated in each call (Suboxone Tablet, Suboxone Film, or Subutex Tablet and generic equivalents), and analyzed that information. RBP paid the companies to conduct the study.

150. Baxter said that the study’s so-called “root cause analysis” would be significant. In July 2012, after consulting with RBP’s general counsel, Baxter sent an email to RBP’s President, stating that if the study found that Film’s packaging caused there to be fewer unintended pediatric exposures, *i.e.*, if it found that the packaging was a “root cause” of the fewer pediatric exposures, then it may be appropriate to withdraw Tablet from the market.

151. On August 31, 2012, Reckitt and RBP’s contractors provided Reckitt and RBP with an “interim report” that failed to include any finding that Film was safer than Tablets with regard to accidental child exposure, or caused any drop in exposures. The interim report stated, “*there remains considerable uncertainty in our ability to use root cause analysis* for identifying the role of select factors in these unintentional pediatric exposures,” and that the data was “*insufficient to make any final conclusions regarding the severity of effects associated with specific buprenorphine medications or the child-resistance efficacy of product packaging types.*”

Disappointed with the report's findings, the RBP manager overseeing the project stated that the interim report was a "worthless, empty shell."

152. On September 13, 2012, the RBP Medical Affairs Manager overseeing the work underlying it emailed MassHealth's pharmacy director. The email stated that children exposed to Tablets got sicker (or, had "more serious sequela") than those exposed to Film, and that certain deaths were associated with Tablets. This statement, however, was not supported by any study. Plus, the Medical Affairs Manager had not discussed her message with others at RBP before sending it to MassHealth. When RBP's director of government affairs received a copy of the email, he said, "I have a serious problem with this," because he was not consulted.

153. On September 14, 2012, RBP executives caused the preparation of a public relations strategy for discontinuing Suboxone Tablet, indicating that RBP would dispel the "[p]erception of discontinuation as a means for blunting generic/competitive entry" and convey a "'[w]e must be responsible' sentiment."

154. Also on September 14, 2012, Reckitt and RBP's contractors provided Reckitt and RBP with a three-page "executive summary" that failed to include any finding that Film was safer than Tablets with regard to accidental child exposure, or caused any drop in exposures. The summary stated that, based on mentions in notes of telephone calls to poison control centers, the rates of unintended pediatric exposure were:

- a. 6.25 per 10,000 recipients for Suboxone Tablet,
- b. 2.51 per 10,000 recipients for Subutex Tablet and generic equivalents, and
- c. 0.71 per 10,000 recipients for Suboxone Film.

155. Although these rates reflected positively on Film, the contractors stated they could not determine the reasons (or "root causes") for the differences because the data was insufficient. Their analysis did not find that Film or its packaging caused a low rate of pediatric exposure. Nor

did the analysis determine why Subutex Tablet and its generic equivalents – which were sold in conventional medication bottles with child-resistant caps, like Suboxone Tablet – also had a low rate. More generally, the analysis did not find that Film was safer than Tablets. Nor did it find that Subutex Tablet and generic equivalents were safer than Suboxone Tablet. The analysis stated that “*any results related to the original packaging should be interpreted with considerable caution*” because many of the poison control center notes did not indicate whether the drug had been in the packaging or left outside the packaging by an adult. Further, a mention of a drug in a note of a telephone call to a poison control center does not necessarily mean that anyone ingested the drug or was hurt. Plus, Film had been marketed as safer than Tablets during the study period, potentially creating an indication bias whereby more safety-conscious people received it. And Film had been available in the market for a shorter time than Tablets, reducing the amount already in circulation at the start of the study period. Also, the severity of the unintended pediatric exposures, *i.e.*, whether the children got sick, and if so, how sick, was not analyzed. The limited nature of the analysis did not provide a basis for RBP to advertise that Film was safer than Tablets.

156. As discussed above, Baxter had said that discontinuing Tablet could be appropriate if the study found that Film’s packaging caused a lower rate of pediatric exposure. But it had not found that; the root cause analysis had been inconclusive. Nevertheless, just a few days later, on September 18, 2012, Reckitt and RBP sent a “Notice of Discontinuance” of Suboxone Tablet to the FDA, stating that the reason for the discontinuance was “increasing concerns regarding pediatric exposure to” Suboxone Tablet. Thaxter and Kapoor approved the notice, even though they knew the primary reason for the discontinuance was to delay FDA approval of generic Suboxone. In fact, the discontinuance only applied to the U.S. market; Reckitt continued to sell Suboxone Tablets in its foreign markets.

157. On September 25, 2012, Reckitt and RBP submitted a citizen petition to the FDA, signed under penalty of perjury by Baxter, falsely stating that RBP discontinued Suboxone Tablet “due to safety concerns” about Tablets, and asking the FDA not to approve generic versions of Suboxone Tablet. Thaxter and Kapoor approved the petition, even though they knew the primary reason for the discontinuance was to delay FDA approval of generic Suboxone.

158. The petition referenced a new, five-page version of the executive summary, which Reckitt and RBP executives and others had participated in altering, but kept dated September 14, 2012, concealing the fact that it was altered from the version they originally cited for discontinuing Suboxone Tablet. *The alterations included deleting the statement that “any results related to the original packaging should be interpreted with considerable caution.”* See Exhibit F at 3, attached hereto. The alterations also included the addition of the following materially misleading and inaccurate Conclusion:

Rates of unintentional exposure of children less than six years of age to buprenorphine were consistently and significantly higher for single- and combination-ingredient tablets than for combination-ingredient film.

Id.

159. The sworn petition also stated that RBP was discontinuing Suboxone Tablet due to safety concerns about unintended pediatric exposure, based on the executive summary. It argued that the FDA should not approve generic versions of Suboxone Tablet because it was unsafe. Reckitt and RBP’s petition did not mention any of the numerous caveats included in the executive summary.

160. On September 25, 2012, Reckitt posted on its website a press release stating that Suboxone Tablet was discontinued “due to increasing concerns with pediatric exposure.” Thaxter and Kapoor approved the press release, even though they knew the primary reason for the discontinuance was to delay FDA approval of generic Suboxone.

161. Reckitt, through RBP and its executives, employees, and agents, used the discontinuation of Suboxone Tablet to fraudulently market Suboxone Film. Beginning September 18, 2012, and continuing during the Class Period, they prepared and caused to be prepared, and shipped and caused to be shipped to their executives and employees and others throughout the United States, letters signed by RBP's medical director and used to promote Suboxone Film that contained materially false and fraudulent statements and representations, including the following:

(i) "Dear Patient . . . The decision to take Suboxone Tablets off the market was a voluntary choice made by [RBP] ***as a result of recent information the company received showing higher rates of accidental pediatric exposure (when a child accidentally takes the medicine) linked with the tablet form.*** If you are currently taking Suboxone Tablets, continue taking your medication and ***ask your doctor about how to transition to Suboxone Film.*** . . ."; and

(ii) "Dear Healthcare Professional . . . ***The decision to discontinue Suboxone Tablets was based on accumulating data demonstrating significantly lower rates of accidental pediatric exposure with Suboxone [Film] compared with the tablet form[.]***"

162. On December 4, 2012, the lead researcher from one of Reckitt and RBP's contractors who had reviewed and analyzed notes of telephone calls to poison control centers emailed fellow researchers, stating that by using the research to supposedly justify discontinuing Suboxone Tablet, Reckitt and RBP "played us as a pawn and continues to do so. They are smart people, and they are playing a Machiavellian game."

163. On February 13, 2013, Kapoor discussed Reckitt's upcoming plans to withdraw Suboxone Tablets during a conference call with analysts and investors. Kapoor stated, in pertinent part:

[O]ur decision to withdraw the tablet was made independent of the Citizens Petition. We announced the decision to withdraw, before we filed the Citizens Petition. It's got nothing to do with it.

So we withdraw the tablet anyway. And ***we withdraw the tablet because we strongly believe that there is an issue of patient safety here, patient sorry, safety around the patient, pediatric safety.*** And ***it's done on that principle.*** And,

therefore, irrespective of the outcome of the Citizens Petition, our plan to withdraw it continues to take place.

164. In response to Reckitt's citizen petition, on February 22, 2013, the FDA concluded that the withdrawal of Suboxone Tablets for safety reasons was not necessary, noting that Reckitt's study was inconclusive and that accidental pediatric exposure to Suboxone had actually been on the decline, which was attributed to new labeling requirements. The FDA knew that Reckitt's citizen petition was a thinly veiled attempt to delay the entrance of generic Suboxone Tablets into the market. In its response to Reckitt's petition, the FDA stated:

Reckitt's own actions also undermine, to some extent, its claims with respect to the severity of this safety issue. *Notwithstanding the availability of data showing an increasing rate of accidental pediatric exposure through at least the first part of 2010, and the first report of pediatric death in June 2010, Reckitt did not discontinue marketing of the tablets in multi-dose containers for more than two years.* As recently as August 2012, Reckitt indicated to FDA its view that the [Suboxone] REMS, which is designed to mitigate the risks associated with that drug, had been successfully implemented and that it was not proposing any changes. *The timing of Reckitt's September 2012 announcement that it would discontinue marketing of the tablet product because of pediatric exposure issues, given its close alignment with the period in which generic competition for this product was expected to begin, cannot be ignored.*

165. In other words, Reckitt had been selling Suboxone Tablets for years, despite possible safety concerns. Indeed, RBP continued throughout the Class Period to sell Suboxone Tablets in Canada, Europe, South Africa, Asia, and New Zealand – even after its withdrawal of the Tablets from the U.S. market.

166. In discussing the suspicious timing of Reckitt's citizen petition so close to the period in which generic competition for the Tablet was expected to begin, the FDA noted that Reckitt had gained access to information about the timing of generic applications for Suboxone Tablets as a result of efforts to secure Reckitt's participation in a single shared REMS for generic Tablets.

167. Revealing its true view of Reckitt's citizen petition as a sham, the FDA referred Reckitt to the FTC to investigate and address Reckitt's anticompetitive business practices. The FTC ultimately concluded, in 2020, that RBP's conduct violated antitrust laws and that it abused the citizen's petition process. As part of its \$10 million settlement with the FTC in July 2020, Indivior agreed to provide certain disclosures to the FDA and FTC for any future citizen petitions, including: (1) all studies and data on which the citizen petition relies; and (2) all studies or data within Indivior's knowledge or possession that address the validity or strength of one or more of the material contentions of the citizen petition.

168. Despite the FDA's rejection of all of Reckitt's claims, the citizen petition resulted in five months of delay in the time it took for the petition to be denied. Concurrent with its response to Reckitt's citizen petition, the FDA approved generic Suboxone Tablets for sale. Thus, given that Reckitt was making approximately \$1.5 billion in revenue from Suboxone in 2012, the delay likely resulted in more than \$600 million in Suboxone Film sales for Reckitt.

169. Despite the FDA's February 22, 2013 negative response to the citizen petition, Defendants nonetheless informed investors in Reckitt's 2012 Annual Report, published on or about March 27, 2013, that Reckitt voluntarily discontinued Suboxone Tablets in the U.S. "due to increasing concerns with paediatric exposure." Defendants reiterated the false basis for the discontinuance in Reckitt's 2013 Annual Report, published on or about April 3, 2014.

G. Defendants Misled Medicaid Administrators Concerning the Safety of Suboxone Film

170. Between May 2011 and approximately December 2013, Reckitt, through RBP and its executives, employees, and agents, made, and caused to be made, false and misleading statements to state Medicaid administrators, claiming that Suboxone Film was safer than Tablets with respect to misuse, abuse, diversion, and accidental child exposure. These materially false and misleading statements included representations by employees, physicians, and agents, acting on

behalf of RBP. *See* Indictment, Ex. A at ¶¶91-96. For example, on May 30, 2011, RBP's publicist provided the following quote for an article in *Alcoholism & Drug Abuse Weekly, News for Policy and Program Decision-makers*: "the main value of [Suboxone Film] is that it is less easily diverted because physicians can track the numbered unit-dose packaging, and it is safer because the packaging is child-resistant." RBP's marketing director emailed Thaxter and RBP's president, medical director, and others, stating that "[t]here does seem to be some liberty taken with regards to early comments attributed to" RBP's publicist, but RBP did not correct or retract the comments.

171. In addition, the DOJ's prosecution of criminal charges against Thaxter, Indivior, and Baxter in 2020 depict fraudulent efforts in 2011 and 2012 to persuade Massachusetts' Medicaid program, MassHealth, the largest Medicaid program in the country by volume of addiction-treatment-drug business, to make the Film a preferred drug on the MassHealth formulary.

172. Before December 2012, Suboxone Film was not a preferred drug on the MassHealth formulary and had restrictions on approval for reimbursement. Therefore, to further boost profits, RBP and Thaxter made persuading MassHealth to expand coverage of Suboxone Film a priority. Thaxter and Baxter oversaw these efforts. Baxter was familiar with the issue of unintended pediatric exposure and RBP's use of analyses of unintended pediatric exposure. He attended meetings and working sessions where RBP personnel and others discussed announcing that there was a negative safety issue with Tablets and that the Film offered superior safety, and highlighting the issue of unintended pediatric exposure, even though there were no scientific studies to support this position. *See* Ex. E.

173. On January 11, 2011, Thaxter received an email from an RBP Senior Manager, indicating that MassHealth was considering expanding coverage of a non-opioid drug (not

Suboxone) for use in the treatment of opioid addiction/dependence. In response, Thaxter emailed RBP's top State Government Affairs employee, copying its Vice President for Sales and Marketing, and asking for a "strategy to counter" MassHealth's consideration of the alternative drug. RBP's top State Government Affairs employee replied to Thaxter by email, laying out a multi-pronged plan that included using "a Strategic Communications approach to bring forward previous concerns around Diversion, Misuse and Abuse with the tablet along with the Poison Control data that demonstrates the number of unintended exposures and how [Suboxone Film] holds promise to address" the risk of unintended pediatric exposure.

174. On or about May 16, 2012, after Thaxter failed to secure a meeting with a MassHealth official, RBP's Managed Care Director wrote to Thaxter: "Shaun: Thanks for the efforts . . . We know how important MassHealth is and it is #1 ranked Medicaid [for us] by volume in the U.S. . . . My suggestions (in confidence not to be shared): 1) We build our pediatric poison campaign with the largest poison control centers in Mass. and we demonstrate the public health impact" to MassHealth.

175. During 2012 and thereafter, Thaxter and other RBP executives received data from poison control centers on unintended pediatric exposure for all buprenorphine drugs. In June 2012, Baxter approved RBP's retention of Researched Abuse, Diversion, and Addiction-Related Surveillance System ("RADARS") for access to data from poison control centers for use in analyzing unintended pediatric exposure. During 2012 and thereafter, RBP contracted with RADARS to analyze the data for rates and trends.

176. On October 2, 2012, Thaxter, Baxter, and other employees received an email from RBP's Medical Affairs Manager. In the email, the Medical Affairs Manager stated that a MassHealth official had reached out "requesting a meeting with me in his offices." The Medical

Affairs Manager stated, “I am very excited at this opportunity to share the pediatric data” from RADARS, but asked to attend the meeting alone because “the situation . . . is very delicate.” “You can rest assured,” the Medical Affairs Manager wrote, “that we will have a successful meeting and things will change in Massachusetts.” Thaxter responded: “Sorry I missed the discussion. My contribution is that I would like [Baxter and RBP’s Vice President for Clinical Affairs] to attend the meeting as well. I agree that we commercial people should not attend this meeting.” However, Baxter and the other RBP Vice President did not attend the meeting.

177. On October 9, 2012, RBP’s Medical Affairs Manager met with the MassHealth official and provided a RADARS analysis of unintended pediatric exposure data from poison control centers nationwide. Following the meeting, the Medical Affairs Manager emailed a report of the meeting to Thaxter, Baxter, and others, stating that the MassHealth official was “very responsive to the pediatric data,” and added, “[b]ecause RADARS can analyze exposure data to the 3-digit zip code in the US, my next step is that I have asked [RADARS] to do an immediate analysis of the rates of unintended pediatric exposure to buprenorphine tablets in Massachusetts as the utilization of tablets is high there and I expect that the rates of exposure follow suit. I am going to follow up with a telephone meeting with [the MassHealth official] to share this information.” The Medical Affairs Manager then asked RADARS for an analysis of unintended pediatric exposure data for Massachusetts only, *i.e.*, a Massachusetts-specific analysis, to provide to the MassHealth official.

178. The next day, RADARS provided the Medical Affairs Manager with the Massachusetts-specific analysis, which showed the rates of unintended pediatric exposure in three categories of drugs: (1) Suboxone Film; (2) Suboxone Tablet; and (3) buprenorphine-only tablets such as the Subutex Tablet and generic equivalents (“mono tablets”), which are packaged in the

same manner as the Tablet. The analysis did not align with the Medical Affairs Manager's expectation that she had expressed to Thaxter, Baxter, and others, as it showed that, in Massachusetts, there were 2.7 exposures per 10,000 units for the Film, 3.3 exposures per 10,000 units for the Tablet, but only 1.8 exposures per 10,000 units for the mono tablets. Thus, the Film did not have the lowest rate of unintended pediatric exposure.

179. In response to these findings, the Medical Affairs Manager emailed RADARS, copying Baxter, and asked if she could "just add the mono and combination tablets to see the difference from film?" RADARS replied-all, indicating that it would obtain additional calculations and data that would be needed. Baxter responded to the Medical Affairs Manager only, indicating that he had reviewed and comprehended the data RADARS sent, making the observation that the data "actually appear[ed] to make mono tablets look best or am I mi[s]reading?"

180. As a matter of mathematics, it is incorrect to "just add" rates together, because they may involve different denominators. As a matter of science, it is improper to change data from a study to get a certain result.

181. On October 16, 2012, the Medical Affairs Manager sent the MassHealth official an email containing false and misleading statements. The email contained an implementation of the question she had posed to RADARS and Baxter – a calculation of the unintended pediatric exposure data for Massachusetts that added the two tablet rates together – despite knowing full well that adding the two tablet rates together would not provide an accurate calculation. The Medical Affairs Manager indicated to the MassHealth official that she had received the calculations from RADARS when, in fact, she had not received them from RADARS, but had done the calculations herself. As a result, the manipulated data indicated that the Film had the

lowest rate of unintended pediatric exposure in the state, when it was in fact the mono tablets that had the lowest rate.

182. The Medical Affairs Manager also falsely stated to the MassHealth official in the email that Suboxone Film had the lowest rate of unintentional pediatric exposure in Massachusetts when, in fact, buprenorphine-only tablets like Subutex Tablet had the lowest rate in Massachusetts, according to the RADARS data. The Medical Affairs Manager forwarded her email to Baxter, stating that she sent it to the MassHealth official to “help us get some movement in Mass.” Baxter did not respond to this email, even though he had previously remarked on the correct RADARS data, which had shown a different result.

183. On November 19, 2012, in response to a follow-up question from the MassHealth official about the email described above, the Medical Affairs Manager failed to reveal facts material to MassHealth prior to its updated formulary decision. In fact, she did the exact opposite, sending a chart with information from an RBP promotional brochure that referenced pediatric data comparing the two products that contained buprenorphine and naloxone, indicating that the Film had a substantially lower rate of pediatric exposure than Suboxone Tablets. The chart did not include the third line of data known to the Medical Affairs Manager that showed Subutex Tablets, which were sold in bottles like Suboxone Tablet, having a lower rate of pediatric exposure than Suboxone Film. By failing to include this data, the Medical Affairs Manager reinforced her false and misleading claim that Massachusetts-specific data showed the Film as having the lowest rate of unintended pediatric exposure in the state.

184. Baxter was not copied on this email; however, RBP omitted this third line from marketing brochures its salespeople showed doctors and pharmacists that Baxter approved. Furthermore, around the same time, another RBP marketing employee emailed Baxter, stating, “I

couldn't help but notice that the chart did not show the [buprenorphine-only tablets] line. Does that mean we can also show the graph without [that] line? That would make such a huge difference!" Baxter simply responded, "That chart is now published so knock [sic] yourself out!" Thus, Baxter was aware of what was happening and was actively participating in the discussion.

185. After receiving RBP's Medical Affairs Manager's emails, the following month, in December 2012, MassHealth issued a press release, citing to RBP's nationwide pediatric exposure-rate data, announcing that it would "provide access to the unit-dosed film formulation to those members prescribed Suboxone who live in households with children less than six years of age[.]" Dr. Paul Jeffrey, the Director of Pharmacy for MassHealth, emailed his supervisor, the Director of MassHealth, stating that he relied on the Massachusetts-specific data RBP sent him. Specifically, he stated, "the delta in exposure rates in Massachusetts is significantly smaller than the rest of the country, but still sufficiently compelling to justify this policy change." Additionally, Dr. Jeffrey testified during Thaxter's October 22, 2020 sentencing hearing that MassHealth's receipt of this data "was the pivot point upon which we made that decision," and if he knew that "the exposure to the film was greater than the exposure of the tablets, then . . . I would have stopped any process to change our policy decision around the film."

186. In April 2013, RBP had a corporate conference in Florida. At the conference, the Medical Affairs Manager made a speech to RBP employees working as lobbyists. In the speech, she said that the Massachusetts-specific rates she had sent to Dr. Jeffrey were a "slam dunk," and "helped" get MassHealth to cover Film. She then added that the following quarter, she "looked at Massachusetts again" and the data "flipped," indicating that Suboxone Tablet had the lowest rate of unintended pediatric exposure in Massachusetts. However, she stated that she did not provide this information to MassHealth, reasoning, "don't ask, don't tell."

187. For approximately three years, RBP failed to correct the false and misleading statements made to MassHealth about unintended pediatric exposure in Massachusetts. During or before that time, Baxter emailed fellow RBP personnel reporting that the FDA appeared to have denied RBP the ability to make a promotional claim that Suboxone Film provided additional safety with regard to unintended pediatric exposure, noting that no studies on the issue had been performed. It was not until December 2015, in the midst of the government's investigation of RBP/Indivior and knowing full-well that the government was going to get access to the false data, and after Reckitt had demerged RBP, that Thaxter and Baxter approved sending a correction letter to MassHealth.

188. Ultimately, the conduct described above resulted in widespread criminal liability, including guilty pleas by Thaxter, Baxter, and Indivior Solutions. And as part of Indivior's settlement with the DOJ, Indivior agreed to be prohibited from using data obtained from surveys of healthcare providers for marketing, sales, and promotional purposes.

189. A related aspect of Reckitt's multifaceted plan to coerce MassHealth to add Suboxone Film to its formulary included Reckitt hiring purportedly independent physicians to lobby MassHealth. Dr. Jeffrey, who testified during Thaxter's sentencing hearing, is the principal decision-maker concerning whether MassHealth covers a particular drug. In 2010, when Suboxone Film was first introduced to the market, RBP attempted to persuade Dr. Jeffrey to prefer the Film over the Tablets. MassHealth declined to cover the Film, however, and instead preferred Suboxone Tablets based on the lower cost of the Tablets.

190. Persuasion turned into a nefarious conspiracy to coerce in February 2011, when RBP lobbyists began working with a public relations firm to initiate a strategic communications plan to help garner MassHealth formulary approval for Film. RBP's marketing director indicated

that she opposed this idea. In response, one of the lobbyists said RBP's marketing director was "clueless," and stated that they needed to hire "a guerilla" for the strategic communications. The marketing director forwarded this email to Thaxter. Thaxter responded that the lobbyist's statements were "outrageous," and he would have a further discussion with the marketing director.

191. Although Thaxter said that RBP's lobbyist's statements were outrageous, the lobbyists continued with the strategic communications plan. The lobbyists, together with the public relations firm, then found a purported doctor, Gere Unger ("Unger") who had previously been convicted of mail fraud.¹³ They had Unger begin writing letters to and about MassHealth, advocating for Suboxone Film. The lobbyists said that the purported doctor's initial letter would "tighten a sphincter or two" and raise the heat on MassHealth officials to "Dante's inferno." It is unclear whether this letter was sent.

192. In 2011, Dr. Jeffrey began to receive letters from Unger. Unger represented himself as a physician who was representing veterans of the armed forces, and he wrote to Dr. Jeffrey and his superiors on numerous occasions regarding the lack of coverage for Suboxone Film by MassHealth. For example, in April 2011, Unger wrote an email to Dr. Jeffrey's immediate boss, Dr. Judith Steinberg, stating that "Diversion cannot occur with the sublingual film and its packaging," and "[t]he decision not to approve the sublingual film on MassHealth endangers a multitude of children, *placing them in the cross hairs of a bureaucrat's selfish lapse in judgment abusing their discretion.*" Dr. Steinberg forwarded Unger's email to Dr. Jeffrey, as well as her boss and the Chief Medical Officer for MassHealth. Dr. Jeffrey understood the email as an attempt to convince him to change his decision to exclude Suboxone Film from coverage. Dr. Jeffrey

¹³ Unger's prior mail fraud conviction is discussed in *United States v. Unger*, 269 F. App'x 62 (2d Cir. 2008). The decision states that he conceded he did not actually possess a medical license.

responded to Dr. Steinberg, “Among the numerous misstatements of fact is the assault on my character, however misguided. . . . I’m suspicious he is not, in fact, misguided but rather is guided to his peculiar conclusion by an unfriendly party. If Reckitt is participating in character assassination as I suspect, I wonder if I should do something about it.”

193. In another email to Dr. Jeffrey and Dr. JudyAnn Bigby, the Massachusetts Secretary of Health and Human Services – the boss of Dr. Jeffrey’s boss – Unger wrote, “What is truly amazing is that Drs. Bigby and Jeffrey still contend that there’s a generic Suboxone,” and proceeded to outline Reckitt’s false talking points about the supposed benefits of Film over Tablets, including less opportunity for diversion and accidental child exposure. Unger compared the “inaction by the policymakers of MassHealth” to “Strom Thurmond’s filibuster in opposition of the Civil Rights Act of 1957. That being private discrimination caused by the acts of government officials resulting in racial subordination.”

194. During his testimony, Dr. Jeffrey was shown an email thread wherein the above exchange was forwarded by Unger to a Reckitt sales and marketing representative and to David Byram. Byram was RBP’s Director, Public Sector, where his responsibilities included directing a “team of 7 field-based State Government Affairs Managers accountable for securing formulary access and delivering on net revenue targets.” Byram responded, in part, “*Looks hopeful.*”

195. When shown Byram’s email, Dr. Jeffrey agreed that it would have absolutely mattered to him that RBP/Indivior employees were coordinating with Unger because “it speaks of a conspiracy to influence my decision-making process . . . and/or implies that Gere Unger was an unannounced employee of Reckitt Benckiser, both of which are material concerns.” Moreover, Unger is a convicted felon who served prison time for mail fraud. Unger has also been charged with practicing medicine without a license.

196. In addition to Unger, Dr. Jeffrey said that “there was a letter-writing campaign that came in from dozens, perhaps, of individuals across the state that were expressing the desire of those correspondents for MassHealth to provide coverage for Suboxone film.”

197. In May 2012, Thaxter attempted to set up a meeting with Dr. Jeffrey through an intermediary concerning “the course of events that had occurred in Massachusetts,” demonstrating Thaxter’s knowledge of RBP’s conspiratorial scheme to influence MassHealth. Dr. Jeffrey declined to meet with Thaxter for what he presumed would be an apology “[b]ecause I had no trust in the company by that point. . . . It wasn’t just the Unger situation[,] but . . . that was a large part of it.”

H. Defendants Marketed Suboxone Film to Doctors Whom They Knew Were Illegally Prescribing It in Order to Switch Patients to Film Prior to Introduction of Generic Tablets

198. Beginning on April 9, 2009 and continuing throughout the Class Period, Reckitt, through RBP and its executives, employees, and agents, induced and procured physicians at various locations throughout the United States whom they knew were prescribing buprenorphine-containing drugs to more patients at a time than allowed by federal law,¹⁴ at daily doses higher than 24 mgs of buprenorphine (*i.e.*, in excess of the maximum dose of any demonstrated additional clinical advantage), and in a careless and clinically unwarranted manner, in order to switch their prescribing to Suboxone Film. Additionally, RBP salespeople provided marketing materials, billing advice, and access to lunch and dinner events to the same physicians whom they knew were prescribing buprenorphine-containing drugs to more patients at a time than allowed by federal law. These physicians took part in RBP’s “Treatment Advocate” speaker program.

¹⁴ The Drug Addiction Treatment Act of 2000 (the “DATA”), as amended in 2006, provided that physicians with their DATA certification could prescribe Suboxone to up to 30 patients concurrently in their first year of certification, and up to 100 patients concurrently thereafter.

199. One way in which RBP encouraged physicians to prescribe Suboxone Film was by including them in RBP's internet and telephone referral program, called "Here to Help." Patients and prospective patients could use the "Locate a Doctor" tool on the Here to Help website to find physicians prescribing buprenorphine-containing drugs, and could call the Here to Help hotline to receive information about certain physicians and have the call transferred to a physician's office to schedule an appointment. RBP salespeople told physicians that Here to Help was "like a concierge service." Thaxter attended presentations in which RBP personnel stated that the program was about "building brand loyalty," and could "accelerate film share capture," meaning increase sales of Film.

200. RBP executives, employees, and personnel knew from statistical and firsthand reports that certain physicians had prescribed buprenorphine-containing drugs to substantially more patients at a time than allowed by the DATA, at daily doses higher than 24 mgs of buprenorphine, and in a careless and clinically unwarranted manner. No later than April 2009, RBP managers began receiving statistical reports that identified physicians overprescribing buprenorphine containing drugs. One RBP manager emailed another, copying RBP's medical director, stating, "It takes only a short time perusing the [statistical reports] to realize that we have some serious breaches of [the DATA law's cap on the number of patients a physician may treat] along with very careless and clinically unwarranted prescribing behaviors (% of patients above 24mg)," and certain physicians "need to be removed from the [buprenorphine] practice arena." RBP managers also received firsthand reports from RBP salespeople and medical advisors that particular physicians were engaged in "continuous prescribing to patients known to be trafficking in Suboxone/Subutex"; allowing "prescriptions [to be] given when provider not present in office";

“charg[ing] 400 per month” for prescriptions; and suspected of allowing “overt trafficking in provider’s parking lot.”

201. RBP executives were aware of the careless, clinically unwarranted prescribing. On July 22, 2009, Thaxter wrote to RBP’s vice president for clinical affairs, “I think that the process for reporting rogue physicians is going to be very important.” Thaxter and Baxter attended meetings in which the identifying and monitoring of doctors was discussed. At a meeting on July 14, 2010, for instance, according to Baxter’s notes, RBP’s leadership team met and discussed data indicating that the 564 highest-prescribing physicians in the United States prescribed buprenorphine-containing drugs to an average of more than 200 patients at a time – more than double the amount permitted by law – and the highest prescribers, which RBP called “Super P8s,” accounted for 33% of RBP’s business. The RBP leadership team discussed that these physicians’ prescribing needed to be “dissect[ed]” to “determine impact on diversion.” Yet RBP did not use this information to remove overprescribing doctors from the Here to Help telephone hotline.

202. Reckitt, through RBP, kept detailed records of the prescribing activity of physicians in its Here to Help and Treatment Advocate programs. The Indictment cites numerous instances demonstrating that RBP continued to include physicians it knew were issuing careless, clinically unwarranted opioid prescriptions in the Here to Help and Treatment Advocate programs, and otherwise market Suboxone Film to them. *See* Indictment, Ex. A at ¶¶102-143. For example, on September 10, 2013, an RBP Sales Representative wrote to an RBP Risk Manager, “Firsthand report: Doctor A is ‘[m]assively over the cap [the maximum patient limit allowed under the DATA] . . . she also overdoses. . . . This has been an ongoing problem since I started that only continues to get worse.’” *Id.* at ¶111. On April 8, 2010, an RBP Sales Supervisor wrote to the RBP National Sales Supervisor, “Email: Doctor B is ‘well over the allowed patient cap,’ and

Doctor C's office 'will prescribe to as many patients as they can fit in [while physicians are] in about 2-3 hours each week. In that time they quickly see the patient & provide a script[.]'" *Id.* at ¶120.

203. Recognizing the wrongfulness of this conduct, in its settlement with the DOJ, Indivior agreed to remove healthcare providers who are at a high risk of inappropriate prescribing from its promotional programs.

I. Defendants Promoted Suboxone Film Using False and Misleading Marketing Materials

204. Beginning in 2010 and continuing during the Class Period, Reckitt, through RBP and its executives, employees, and agents, prepared and caused to be prepared written marketing materials used to promote Suboxone Film that contained false statements, including the following:

- (a) Suboxone Film was "Helping Address Public Health Needs";
- (b) Suboxone Film could "Help Address Misuse and Abuse";
- (c) Suboxone Film "Can Be Part of the Solution" to "misuse," "diversion and abuse," and "unintentional pediatric exposure";
- (d) "Nearly half of Suboxone Film prescribers surveyed cited 'potential for reduction of abuse and diversion' as a reason to prescribe vs Suboxone Tablet," when in fact, only 28% of the prescribers had cited that supposed reason, many of them after receiving fraudulent sales presentations from RBP;
- (e) A false and fraudulent chart with the heading, "Suboxone Film – Helping to Reduce the Risk of Pediatric Exposure," that purported to depict pediatric exposure data for Suboxone Tablet and Suboxone Film, but intentionally omitted other data from the same study that showed that buprenorphine-only tablets also had low pediatric exposure, and therefore called into question the claim that Suboxone Film reduced pediatric exposure; and

(f) A false and fraudulent pair of charts with the heading, “Suboxone . . . Film – associated with lower rates of diversion and abuse . . .” that purported to depict diversion and abuse data for Suboxone Tablet, buprenorphine-only tablets, and Suboxone Film, but intentionally omitted two other charts from the same page of the same study that showed that Suboxone Tablet and buprenorphine-only tablets had diversion and abuse rates similar to Suboxone Film during certain time periods, and therefore called into question the claim that Suboxone Film was associated with lower rates of diversion and abuse.

205. As discussed above, Thaxter, Indivior Solutions (RBP’s successor), and Baxter pleaded guilty to criminal charges associated with their failure to prevent and promptly correct the false and misleading charts described in ¶204 (e) and (f).

206. On various dates, Reckitt, through RBP and its executives, employees, and agents, mailed copies of marketing materials described in ¶204 above, from a contractor in New Jersey to RBP sales representatives throughout the United States.

J. Suboxone Film Was Exceptionally Lucrative to Reckitt

207. Defendants’ scheme to fraudulently inflate sales of Suboxone Film was a success. In 2010, Suboxone was the 25th-highest selling pharmaceutical by dollar volume worldwide – despite qualifying as an orphan drug that Reckitt convinced the FDA would not be profitable. By mid-2012, the Film accounted for over 70% of Suboxone prescriptions, and by the time the generic Tablets received FDA approval in February 2013, 85% of Suboxone prescriptions were written for the Film instead of the Tablets. The profit margins for Suboxone Film were more than double Reckitt’s average profit margins.

208. Between 2010 and 2014, Reckitt’s revenues from sales of Film increased ten-fold to more than \$840 million annually. Between 2010 and 2014, RBP and Reckitt received approximately \$2.9 billion in cumulative revenues from sales of Film, as follows:

Year	Film Revenue
2010	\$83,328,721
2011	\$400,615,412
2012	\$666,695,781
2013	\$887,469,559
2014	\$843,047,500

209. In or about the same years, Medicaid payments for Film totaled approximately \$1 billion and Medicare payments for Film totaled approximately \$379 million, as follows:

Year	Medicare	Medicaid
2010	\$2,134,000	\$7,136,000
2011	\$26,188,000	\$108,079,000
2012	\$70,329,000	\$211,294,000
2013	\$132,984,000	\$326,666,000
2014	\$147,704,000	\$386,685,000

210. Between 2011 and 2013, Reckitt's sales of all Suboxone drugs reached nearly \$1.5 billion per year, as follows:

Year	Total Suboxone Revenue
2011	\$1,221,147,000
2012	\$1,491,897,000
2013	\$1,403,762,000

211. In September 2012, Reckitt stated that it would give "special recognition awards" of thousands of shares of Reckitt stock to approximately ten RBP executives and managers for the commercial success of Suboxone Film, saying it had "created a long-term sustainable business model" for RBP.

212. On August 5, 2013, Thaxter emailed Kapoor and others, stating that Suboxone Film's share of the market had grown to 69.1%, which was "almost enough to make you wonder when we will break through the 70% share barrier?" Kapoor replied-all, "I agree, our US team has done a fantastic job of defending our film share thus far."

213. On November 17, 2013, Thaxter stated to an RBP manager that in switching physicians, pharmacists, healthcare benefit programs, and others to Suboxone Film, RBP had achieved “the best format conversion ever in the history of the industry.”

K. Reckitt Demerged RBP to Rid Itself of Suboxone Liabilities

214. After these events took place, Reckitt demerged RBP on December 23, 2014, and it became a company known as Indivior. A demerger is the converse of a merger or acquisition. It describes a form of restructure in which shareholders in the parent company (Reckitt) gain direct ownership in the demerged entity (Indivior).

215. Reckitt announced its plans to demerge RBP in late July 2014 – after a federal investigation had already begun – and on December 11, 2014, Reckitt shareholders approved the demerger.

216. As part of the demerger, Reckitt shareholders received one Indivior share for each Reckitt ordinary share held. Reckitt recognized a gain on the demerger of approximately £1.3 billion (\$2.0 billion).

217. In demerging RBP, Defendants attempted to simultaneously insulate Reckitt from liability by distancing Reckitt from RBP, while continuing to profit from their fraudulent Suboxone scheme. Defendants accomplished this by inserting provisions into the demerger agreement whereby the newly formed RBP successor, Indivior – whose only real assets were Suboxone revenues – agreed to pay Reckitt more than \$500 million in so-called “dividends” in the years after the demerger. Thus, even after nominally giving up control over RBP, Defendants continued to profit from Indivior’s future Suboxone revenue.

218. Moreover, in an attempt to make their demerger plans foolproof, Defendants included an indemnification clause in the demerger agreement, pursuant to which Indivior agreed

to reimburse Reckitt for any liability imposed on Reckitt for matters relating to Indivior's business when it was part of Reckitt, *i.e.*, the RBP business.

219. This is exactly what Reckitt has done: on November 13, 2020, Reckitt filed a claim in the Commercial Court, High Court of Justice of England and Wales, captioned *Reckitt Benckiser Group PLC v. Indivior PLC*, No. CL-2020-000746, to preserve its right to seek indemnification under the demerger agreement. The amount claimed under the submission was £1,073,622,580.51, or approximately \$1.4 billion – the amount Reckitt paid to the U.S. government to resolve its own potential criminal and civil liability.

220. After cutting ties with RBP, Reckitt and its executives continued to conceal their fraud throughout the Class Period.

DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS MADE DURING THE CLASS PERIOD

221. As a result of Defendants' fraudulent scheme described above, Defendants knew and/or recklessly disregarded that the following statements to Reckitt investors were materially false and misleading and/or omitted to state material facts necessary to make those statements not misleading.

A. The July 28, 2014 Press Release and Conference Call

222. The Class Period begins on July 28, 2014. On that date, Reckitt issued a press release announcing its financial results for the first half of fiscal 2014 ("1H14 Release"). The 1H14 Release stated that Reckitt had achieved net revenues of £4.7 billion, operating profit of more than £1 billion and net income of more than £800 million for the first half of the year, which included sales of Suboxone Film. In addition, the 1H14 Release stated that Reckitt had earnings per share ("EPS") of 111.1p during this time frame. The 1H14 Release also quoted Kapoor as stating that RBP had "the potential to deliver significant long term value creation as a stand-alone

business” and would therefore be demerging from Reckitt. According to the release, “[a] stand-alone business will be best placed to create value for shareholders as it manages the challenges and seizes the opportunities within the field of addiction.” The 1H14 Release stated that RBP accounted for £344 million in net revenue (or 7% of total Company net revenues) and £183 million in operating profit (or about 17% of total Company operating profits) during the first half of the year. It also stated that RBP had an adjusted operating margin of 53.2%, more than double Reckitt’s average.

223. The 1H14 Release described RBP as experiencing “strong” volume growth in Suboxone Film despite a more competitive market environment. It stated in pertinent part:

Reckitt Benckiser Pharmaceuticals (RBP)

HY 2014 net revenue was £344m, a decrease of -8% (constant). In Q2 net revenue was £174m, a decrease of -5% (constant). *The underlying volume growth in prescriptions in the USA throughout the first six months continued to be strong with low double digit growth in this undertreated area of addiction.* There was some erosion of volume market share which exited the period at 63%. There has also been some pressure on pricing, particularly in the second quarter, *due to the competitive environment.*

In non USA markets, progress made in helping more patients continues to be partially offset by government imposed price reductions in a number of markets.

Operating margin declined by -380bps to 53.2% due to a combination of negative volume leverage, pricing, and continued investment in the clinical pipeline.

A third generic buprenorphine / naloxone tablet was approved in July in the USA and we will also experience pressure from the formulary removal from part of the United Healthcare business from 1 July.

224. The statements above in ¶223 were materially false and misleading when made because they failed to disclose that Reckitt’s growth in buprenorphine prescription volume in the United States was due to a scheme to mislead investors and the public regarding the health and safety risks of Suboxone Film. Defendants knew, or recklessly disregarded, these undisclosed facts.

225. The 1H14 Release also claimed that Reckitt and its executives followed a stringent compliance program to ensure that the Company adhered to applicable laws and regulations in its business practices, stating: “The Group maintains and continues to improve a robust compliance training programme and ensures that all executive managers sign an annual disclosure and reporting document certifying compliance with the Group’s Code of Conduct.” Reckitt’s Code of Business Conduct, meanwhile, was signed by Kapoor and claimed that all Reckitt employees “must be seen to be dealing even-handedly and honestly with all its consumers, customers, suppliers, employees, contractors, governments & regulators and others with whom the Company has a relationship,” and also that “[a]ll employees and contractors must be aware of and observe all laws and regulations governing their activities.”

226. The statements above in ¶225 were materially false and misleading when made because Reckitt, through RBP and its executives, employees, and agents, systematically misled payers and healthcare providers regarding the safety of Suboxone Film, promoted Suboxone Film through false and misleading marketing materials, and marketed Suboxone Film to healthcare providers to be prescribed and dispensed in a careless and clinically unwarranted manner. Defendants knew, or recklessly disregarded, these undisclosed facts.

227. The Individual Defendants reviewed and approved the 1H14 Release, which quoted Kapoor at length, and thus were responsible for its contents. In addition, the 1H14 Release was signed by Kapoor and Bellamy, who certified that the information contained therein was prepared in accordance with international accounting standards and fairly presented the risks and uncertainties facing Reckitt, among other representations.

228. Also on July 28, 2014, Reckitt hosted a conference call with analysts and investors led by Kapoor, Hennah, and Thaxter. Hennah presented the financial information included in the

1H14 Release, which included the revenues, net income, and earnings from the sale of Suboxone Film and a discussion of relevant market conditions. Hennah also provided the following commentary on the purportedly strong volume growth in Suboxone Film:

In RBP, the minus 5% revenue decline in quarter 2 was determined by a combination of continuing strong market growth, most notably continuing low double-digit growth and buprenorphine prescription volume in the United States; by a modest reduction in market share in the United States Suboxone market; and by some price pressure.

Looking forward to the rest of the year, we expect continuing strong market growth. Our [film] share in the United States will, however, be reduced modestly by the changes in the United formulary for some of their business, and the approval of [a] third generic Suboxone tablet will also add to the share and price pressure in some parts of the market.

229. The statements above in ¶228 were materially false and misleading when made because they failed to disclose that: (i) Reckitt's growth in buprenorphine prescription volume in the United States was due to a scheme to mislead investors and the public regarding the health and safety risks of Suboxone Film; and (ii) the impact of generic competition on sales of Suboxone was mitigated by Defendants' anticompetitive strategies to thwart generic competitors and extend its Suboxone monopoly. Defendants knew, or recklessly disregarded, these undisclosed facts.

230. During the call, Kapoor expounded on Reckitt's rationale for demerging RBP. He claimed that the success of Suboxone Film had given RBP a "global leadership position" in addiction treatment, and that it was on a solid footing for continued growth. Kapoor stated in pertinent part:

So let me just start with a couple of words on this business, which is: Why do we believe that a standalone RBP is the right thing to do? So, well, let's start with the first thing.

I've always said from January 2012 onwards I've said that RBP is not core to RB. We do not want to be a prescription pharmaceutical company, yet it's very important to wait for a time when we will see the impact of generic entry into its heartland. ***We will wait for the time to see what the impact of that will be in terms***

of market growth rate, in terms of sustainability of film, and then make a determination 12 months or so after that what the right thing to do is.

Well, we now know nearly 12 months after the launch of the film, of the generic tablet, that RBP has actually created a global leadership position in the world of addiction treatment, which is a fast-growing under-served market.

It has also got substantial, I would say, near-term cash flows, mainly from its Suboxone franchise. But although this franchise is under competitive pressure, it still has strong defenses, as you will see later today; [IP], patient and [pre-op references].

231. The statements above in ¶230 were materially false and misleading when made because they failed to disclose that RBP's leadership position in the world of addiction treatment was due to: (i) a scheme to mislead investors and the public regarding the health and safety risks of Suboxone Film; and (ii) anticompetitive practices. Defendants knew, or recklessly disregarded, these undisclosed facts.

232. Kapoor also represented that RBP had a "sustainable business" model and was positioned for "strong medium and long-term growth." He stated in pertinent part:

We believe we have demonstrated strong medium and long-term growth opportunities for this business, and you will see today from Christian the pipeline progress on what we have done with RBP.

But beyond the pipeline that we've developed in-house, we've also signed two very interesting and important licensing deals which we've announced recently: The nasal naloxone spray; and the other one is in the entirely new field of alcohol dependence.

And finally, there are geographic expansion opportunities like the ones that we've used very effectively in Australia that we still believe we can go for.

I believe RBP has created a sustainable business on the back of which it can find its true potential.

233. The statements above in ¶232 were materially false and misleading when made because they failed to disclose that the sustainability of RBP's business was due to: (i) a scheme

to mislead investors and the public regarding the health and safety risks of Suboxone Film; and (ii) anticompetitive practices. Defendants knew, or recklessly disregarded, these undisclosed facts.

234. Hennah then introduced Thaxter, the CEO of RBP, stating that he would provide “more information to investors” in the following main areas: “The prospects for Suboxone film in the USA, including very importantly the strength of its IP [intellectual property] protection; the content stage and strength of the pipeline; potential for licensing and business development-led growth; and the potential for growth outside the USA.”

235. In Thaxter’s prepared remarks, he claimed that Suboxone Film was at the forefront of helping patients suffering from opioid addiction. He claimed the success of the drug was due to its superior performance, safety and efficacy, and that the predominance of Film sales over Tablet sales was the product of Reckitt’s unrelenting focus on patient well-being. He stated in pertinent part:

First of all, one thing that’s been consistent in the 12 years that I’ve been leading this business is that all patients around the world have unrestricted access to high quality treatment services for the chronic relapsing conditions of addiction has been the driving force and the vision of the business. [sic] *The focus on the patient is absolutely essential. To have a leadership model that focus[es] on partnership with governments and all stakeholders to bring better quality treatments to patients is what’s driven the success of our business, and will continue to drive the success of our business in the future.*

The impact of bringing a patient out of addiction treatment into addiction treatment truly transforms the life of that patient and the people around them and their families and friends, and therefore has a positive impact on the communities in which they live.

We know that the lead market that we’ve been working in is the US; that’s where the majority of revenues come from; and therefore, is the focus of my next few slides.

Two years ago, this is where the business was at. The blue star represents the Suboxone film share, the pink star was the Suboxone tablet business at the time, the orange star represents the generic mono buprenorphine and the yellow star represents the recent branded competitor; obviously hadn’t launched at that time.

So in the nine months following where we left off, we continue to drive conversion of patients from tablets onto the film driven by the preference of the patient for the film. They liked it, they preferred it. We presented data previously. The physicians were observing a superior treatment outcome. So we saw by March of last year that the film share had grown to 70% and the tablet business had come down to 15%.

We then withdrew the tablet. At the same time, we experienced the launch of two generic competitors to the Suboxone tablet. So if you look at the bottom of the chart, you see our branded tablet disappeared and was replaced by the generic tablet. No surprise there. *What I think absolutely surprised everybody was the level of resilience that the Suboxone film showed in the face of this generic competition.*

The next material event was last September when Zubsolv, a branded competitor, entered the market. And again, we saw a relatively small impact in the first few months.

We then had the announcement which was made public of the [CBS] formulary loss. *And once again, the film share held up and proved its resilience, even in the light of formulary adjustment.* And what we actually saw with the film was about half the level of loss from the CBS business that you would have expected to see had you modeled with standard industry analogs.

So we now await to see what the impact will be of the recently announced third generic tablet competitor. This will, of course, bring new pressures upon us, and we expect that we will continue to outperform analogs as we move forward.

236. The statements above in ¶235 were materially false and misleading when made because they failed to disclose that: (i) Reckitt's focus was not on the patients who were prescribed Suboxone, rather on Reckitt maintaining its monopoly over Suboxone; (ii) Reckitt's conversion of patients from Suboxone Tablets to Suboxone Film was not driven by the preference of the patient for the Film, rather the conversion was due to Reckitt's coercive and deceptive conduct; and (iii) Reckitt's withdrawal of the Tablet was pretextual and was not due to safety concerns. Defendants knew, or recklessly disregarded, these undisclosed facts.

237. Thaxter credited the exceptional sales growth in Suboxone Film to expanding the network of physicians who were treating patients and to driving patients into treatment. He stated in pertinent part:

So overall, two years ago, we had a film share of 55%, tablet share of 30%, and no generics. In the two years since then, when all the uncertainty over the future of the business in the US was in question, we've actually grown our film share from 55% to 61%. Not only have we grown it, but we've grown it in the context and presence of some pretty aggressive competition.

We've maintained our double-digit market growth. This is something we're very good at. We continue to invest in expanding the network of physicians who are actually providing treatment for patients, and we continue to drive the communication to drive patients into treatment. And we're very confident that we will continue to be successful here.

There's a lot of headroom for growth in the market. As proud as we are, there's 5 million patients who have benefited from treatment since we started business. There's still a lot more patients who need to come in who haven't been treated yet.

Our pipeline has moved on considerably. In the last two years, we've met all of our KPIs that we set ourselves, passed a number of regulatory hurdles since we last met. So we're very pleased with our progress here. And we have also licensed in two new technologies, which Rakesh referred to.

One is arbaclofen placarbil for the treatment of alcohol use disorders; and the other is nasal naloxone, which is an overdose rescue medication which we'll talk a little bit more about. Both of these were on our target list that are in your presentation pack that we said two years ago were in the areas that we were looking to focus and expand our business.

And there are more opportunities moving forward. We continue to look for opportunities in cocaine, methamphetamine and cannabis addiction.

So what about the prospects moving forwards [sic] for the Suboxone film? Well, the data has already demonstrated that it is very clearly the preferred product, not only by patients, not only by physicians, but also by payers.

238. The statements above in ¶237 were materially false and misleading when made because they failed to disclose: (i) that Reckitt's growth in Film share was due to a scheme to mislead investors and the public regarding the health and safety risks of the Film and anticompetitive practices; (ii) the illicit nature of the marketing and promotional schemes that fueled Reckitt's expansion of the network of physicians who were providing treatment for patients with Suboxone Film; and (iii) that the supposed preference of patients, physicians, and payers for

Suboxone Film was due to Reckitt's coercive and deceptive conduct. Defendants knew, or recklessly disregarded, these undisclosed facts.

239. Thaxter also stressed that Suboxone Film's superiority to alternatives had led to a preference for the drug by patients, doctors and payers. He stated in pertinent part:

We know that patients prefer the medication experience. Physicians are very happy that their patients are stable and doing well on their medication. And all of this, of course, means that payers are getting a better return on the investment that they are making in providing a treatment to the patient and making that treatment available.

The physician treatment network continues to expand. There are over 25,000 registered physicians. They have excellent access; over 91% formulary access. So there's no problem with patients being able to access physicians or their medication. And the film has strong patent protection, multi-layered protection that now extends to 2030.

So here's just some specific data to share with you, what patients and physicians have said about the film. ***But I think the resilience of the film and its market share performance is the best indicator of their preference.***

So not only do patients and physicians prefer the film, so do payers. And this preference of the patient and the physician is very important to the payer, because the payer doesn't want to disrupt patients who are stable in treatment. Whilst they want to provide access to other medications that might cost them less money, they don't want to disrupt the patient. So if the patient and the physician are happy, that's very compelling.

Not being in treatment has a high cost to society. Therefore, there's a very compelling pharmaco-economic benefit to payers if they can retain patients in treatment. So a stable, happy patient is a good patient.

240. The statements above in ¶239 were materially false and misleading when made because they failed to disclose that: (i) the supposed preference of patients, physicians, and payers for Suboxone Film was due to Reckitt's coercive and deceptive conduct; and (ii) Defendants blocked lower-cost generic competition to Suboxone Tablets, causing payers, and patients suffering from opioid addiction, to pay more for Suboxone Film. Defendants knew, or recklessly disregarded, these undisclosed facts.

241. Thaxter further praised the purported safety of Suboxone Film, which he claimed had a lower potential for abuse. He stated in pertinent part:

Since we've launched each of our products, each product has been designed with the intent of being a lower potential for abuse and misuse than the previous products on the market.

And in addition to all these very important clinical benefits, we partner the pharmaco-economic story with a commercial rebate to make the whole package attractive to payers.

And I think this explains why we have 75% of patients [that] can access this medication at Tier 2, which means it's a lower level of co-pay. We obviously offer the patients a coupon to help offset that co-pay. ***So from a financial affordability perspective for the patient, this is very attractive. It works well for the payer,*** and that's why we see about 90% of all prescriptions getting approved.

When you actually look at the economic argument, well, what's the ratio here? Well, according to the WHO, for every \$1 you spend on treatment, society saves \$12. So this really is a very compelling reason for people who pay for treatment why they should pay for treatment. It's very motivating for governments around the world, and it's also very compelling for commercial payers.

So in the short term, we can expect to continue to benefit from market growth, which is something we get better and better at as time goes on. We will see modest pressure in the near term from our competition, particularly from the third generic. And we will continue to invest in our pipeline so that we have opportunities to accelerate our growth when they come to market.

242. The statements above in ¶241 were materially false and misleading when made because they failed to disclose that: (i) Suboxone Film was neither safer nor less susceptible to diversion and misuse than Suboxone Tablets; (ii) Defendants blocked lower-cost generic competition to Suboxone Tablets, causing payers, and patients suffering from opioid addiction, to pay more for Suboxone Film; and (iii) Reckitt's growth in Film share was due to a scheme to mislead investors and the public regarding the health and safety risks of the Film and anticompetitive practices. Defendants knew, or recklessly disregarded, these undisclosed facts.

243. Thaxter represented that RBP was successfully expanding its strategy to grow Suboxone Film sales in the United States to international markets. He stated in pertinent part:

So we've talked about the US, of course, because it is the majority of today's business, but that really means that there must surely be a lot of opportunity around the world to grow and expand the business.

We have a very successful market development model whereby we can go to markets that are very against treating opioid dependence and other disorders. They may have a punitive attitude; they may incarcerate people who are found to be using drugs. *And we . . . can meet those markets successfully through a phase of normalization and medicalization of the disease, and ultimately to provide general treatment in primary care, such as we've done in the US.*

So we've deployed that model very successfully in Australia, and I'd just like to show it as one example, because it's also a market where we have replaced the Suboxone tablet with the film.

So the film is being rolled out around the world. We have it in the US, Australia, Malaysia. The film is coming to Canada, Europe. We're making good progress in China. In fact, full credit to the Chinese Government who have recently decriminalized opioid use. You're now not arrested and put in jail if you're found to be using opioids by the Chinese Government. You're found by the police and you have to go for treatment, which I think is a very, very progressive mindset and a big shift. So full credit to them for that.

244. The statements above in ¶243 were materially false and misleading when made because the statement concerning Reckitt's replacement of Suboxone Tablet with Suboxone Film failed to disclose that Reckitt replaced the Tablet with the Film in the United States through: (i) a scheme to mislead investors and the public regarding the health and safety risks of Suboxone Film; and (ii) anticompetitive practices. Defendants knew, or recklessly disregarded, these undisclosed facts.

245. Thaxter also stated that RBP employed compliance procedures as a key driver of its success. He claimed that these procedures ensured that the "business is really driven by a patient-centric focus." He continued, in pertinent part:

So we have systems. We have processes. We've got compliance. We have regulatory infrastructure. We've got our own sales force; a very talented group of people all around the world who behave as clinical liaisons and partner with governments and have outstanding relationships with physicians to provide treatment for patients. And that's been a key driver of our success. We do, of course, share some services with RB. We're very grateful for the support we've

had from HR, finance and IS, and the product manufacture through the supply chain.

Over the recent months, we've been working very hard to make sure that we have a standalone model so we could operate independently. And to help us get their transitional services, agreements are in place for all of the areas of overlap.

So as I've said, our business is really driven by a patient-centric focus. That's the passion, that's the drive, that's where we are going. And the reason we're able to get there so successfully is because we've built that on a very, very, very solid platform. And the solid platform is the Reckitt Benckiser culture and the discipline and the mindsets that drives a successful business.

246. The statements above in ¶245 were materially false and misleading when made because they failed to disclose that: (i) RBP did not have sufficient and meaningful compliance systems in place; (ii) RBP's sales force was perversely incentivized to make Film sales at all costs or face termination; and (iii) RBP's relationships with physicians was premised on the prescription of Film in an illegal and clinically unwarranted manner. Defendants knew, or recklessly disregarded, these undisclosed facts.

247. After Thaxter's prepared remarks, an audience member questioned him regarding a new injectable product under development: "[C]learly, on the tablets, you actually stopped doing that because you said the film was far superior and safer, and so on and so forth. I presume the injectable is even better than the film, so should we expect the same to happen to film, or do you think the two are likely to be sustained?"

248. Thaxter responded by once again claiming that Suboxone Film had experienced success because it was a far superior product than the tablet, stating:

What I think is important to recognize is that we're not in the business of forcing the market or patients to do anything. I think that we put the film proposition out there for patients and physicians, and we stated our case as to why we thought it was a better technology. And it was really the rapid uptake by patients and physicians, as for the preference.

249. The statements above in ¶248 were materially false and misleading when made because they failed to disclose that Defendants engaged in anticompetitive practices that coerced patients and physicians to use Suboxone Film over Suboxone Tablets. Defendants knew, or recklessly disregarded, these undisclosed facts.

B. The October 21, 2014 Press Release and Conference Call

250. On October 21, 2014, Reckitt issued a press release announcing its financial results for the third quarter of 2014 (the “3Q14 Release”). The Individual Defendants reviewed and approved the press release, which quoted Kapoor at length, and thus were responsible for its contents. The 3Q14 Release stated that the RBP segment had achieved net revenues of £161 million for the quarter, which included sales from Suboxone Film. The 3Q14 Release provided the following update regarding RBP, which claimed that volume growth in Suboxone Film had remained robust despite increased competitive pressures:

Pharmaceuticals (RBP)

YTD 2014 total net revenue was £505m a decrease of -8% at constant rates (Q3 LFL growth of -9%). The underlying volume growth in prescriptions in the US continues to be strong with low double digit volume growth in line with recent market trends.

Volume Film share of total buprenorphine prescriptions in the US has remained robust, at 60% in the face of increased pricing pressures from generic and branded tablets and removal from formulary of part of United Healthcare from 1 July. A fourth generic buprenorphine/naloxone tablet was approved in September, and a branded film competitor is expected to launch in late Q4. We expect trends seen in Q3 to continue into Q4.

Whilst there continues to be clear patient and physician preference for Suboxone Film, as we have always said, this increased competition in the US market place is expected to drive continued pricing pressure, and further share loss in more price sensitive payors.

In non-US markets, ***progress made in helping more patients*** continues to be offset by government imposed price reductions in a number of markets.

251. The statements above in ¶250 were materially false and misleading when made because they failed to disclose that: (i) Reckitt's growth in Suboxone Film share in the United States was due to a scheme to mislead investors and the public regarding the health and safety risks of Suboxone Film; and (ii) the supposed preference of patients and physicians for Suboxone Film was due to Reckitt's coercive and deceptive conduct. Defendants knew, or recklessly disregarded, these undisclosed facts.

252. Also on October 21, 2014, Reckitt hosted a conference call with analysts and investors led by Kapoor and Hennah. In his prepared remarks, Hennah presented on the financial information provided in the 3Q14 Release. He also claimed that RBP was continuing to experience "strong market growth" and that "[t]here continues to be very clear patient and physician preference for Suboxone Film." Hennah stated, in pertinent part:

Now turning to RBP. ***The underlying volume growth in buprenorphine prescriptions in the United States continues to be strong.*** As expected, RBP's share of total buprenorphine prescriptions declined slightly, to around 60%. This was the result of increased pricing pressures from generic and branded tablets; and removal from formulary of part of United Healthcare from July 1.

Strong market growth, some share loss, and some price pressure led to the 9% reduction in constant currency RBP revenue in quarter 3. We expect trends seen in the third quarter, and their impact on our results, to be broadly similar in the fourth quarter.

A fourth generic buprenorphine/naloxone tablet was approved in September. In addition, a branded film competitor may launch a competing product in quarter 4. We firmly believe that this product breaches our IP protection and we have initiated the corresponding legal process.

There continues to be very clear patient and physician preference for Suboxone Film. However, we have always said that increased price competition in the US marketplace will drive some further share loss among more price-sensitive payors. We continue to expect this dynamic to play out in 2015.

253. The statements above in ¶252 were materially false and misleading when made because they failed to disclose that: (i) Reckitt's growth in buprenorphine prescriptions in the

United States was due to a scheme to mislead investors and the public regarding the health and safety risks of Suboxone Film; and (ii) the supposed preference of patients and physicians for Suboxone Film was due to Reckitt's coercive and deceptive conduct. Defendants knew, or recklessly disregarded, these undisclosed facts.

254. In response to an analyst's question regarding generic pricing pressures on Suboxone Film, Hennah offered assurances that the superior qualities of the film would continue to offer competitive advantages, stating: "For the rest of the market, we've – the advantages we have, the clinical advantage we have, *the preference we have, which is very clear among the patients and is very clear among the clinicians*, is reaffirmed every day we're out there, is reaffirmed continually in the market data. We expect that to be a very, very strong influence in the rest of the market."

255. The statements above in ¶254 were materially false and misleading when made because they failed to disclose that the supposed preference of patients and physicians for Suboxone Film was due to Reckitt's coercive and deceptive conduct. Defendants knew, or recklessly disregarded, these undisclosed facts.

256. Additionally, when another analyst asked for "clarification on why the demerger has been able to proceed sooner than was originally planned," Hennah responded as follows:

Yes, surely, why the demerger [was] so quick, well, we're RB and we like to get on things, basically. And the preparations have gone well. Preparations financially, with all the accounts and those things you've got to do; the preparations operationally, making it standalone; the preparations in assembling what we believe is a very good Board, they've all gone well. And we want to get on with things, so why wait? It's as simple as that, really.

257. Thus, even when pushed to explain the timing and rationale behind the merger, Defendants failed to even mention Suboxone, instead hiding the relevant facts behind "portfolio

cleanup” efforts and painting the picture of a general refocus and rebranding of the Company that would bring about future success.

258. The statements above in ¶256 were materially false and misleading when made, as they failed to disclose that the reason Reckitt sought to quickly demerge RBP was because RBP was under federal investigation related to Suboxone and, therefore, Reckitt wanted to rid its books of RBP. Defendants knew, or recklessly disregarded, these undisclosed facts.

C. The November 17, 2014 Demerger Release

259. On November 17, 2014, Reckitt issued a press release announcing the demerger of RBP (the “Demerger Release”). The Individual Defendants reviewed and approved the Demerger Release, which quoted Thaxter and Bellamy at length, and thus were responsible for its contents. The Demerger Release described RBP, now named Indivior, as a “leading international addiction business.” It stated in pertinent part:

- ***The RBP business is a leading international addiction business with net revenues of \$1.2 billion and net income of \$489 million for the year ended 31 December 2013*** (calculated under IFRS for RBP on a “carve out” basis, for which see details in the prospectus published later today). ***80% of net revenues were in the United States, where the RBP business has the leading position in products treating opioid addiction, a growing market. Profits before tax for the year ended 31 December 2013 were \$695 million. Gross assets as at 30 June 2014 were \$455 million.***
- ***Suboxone Film remains the leading treatment for opioid addiction in the US market with approximately 60% market share of the buprenorphine market by volume.***

260. The statements above in ¶259 were materially false and misleading when made because they failed to disclose the fraudulent basis for RBP’s status as a “leading international addiction business” and for Suboxone Film “remain[ing] the leading treatment for opioid addiction in the US market[.]” Defendants knew, or recklessly disregarded, these undisclosed facts.

261. The Demerger Release also quoted Indivior's new chairman of the board, Howard Pien, who stated that "Indivior, under the leadership of Shaun Thaxter, has built a global, industry leading company in addiction treatment" and that "[t]he business has a profitable opioid addiction business and a strong pipeline that has the potential to revolutionise how the chronic disease is treated worldwide." The release quoted Thaxter as stating, in pertinent part:

"I look forward to partnering with the Indivior Executive Committee and Board to further build upon the strong foundation set by Reckitt Benckiser Pharmaceuticals under the guidance of RB as we transition to a sustainable, stand-alone organisation. Our full team – from the Executive Committee to the Board to our employees – is energised by the opportunity *to continue leveraging our unique patient-focused leadership model to expand availability of addiction treatment and improve patient lives across the globe.*"

262. The statements above in ¶261 were materially false and misleading when made because they failed to disclose the fraudulent basis for the profitability of RBP's opioid addiction business. Defendants knew, or recklessly disregarded, these undisclosed facts.

D. The February 11, 2015 Press Release and Conference Call

263. On February 11, 2015, Reckitt issued a press release announcing its fourth quarter and full year 2014 results (the "FY14 Release"). The Individual Defendants, other than Thaxter, reviewed and approved the press release, which quoted Kapoor at length, and thus were responsible for its contents. The FY14 Release stated that Reckitt had achieved £3.2 billion in net income for the year, which included sales from Suboxone Film. In addition, the FY14 Release stated that Reckitt had EPS of 441.1p during this time frame. The FY14 Release stated that RBP accounted for £677 million in net revenue (or 7% of total Company net revenues) and £369 million in operating profit (or about 15% of total Company operating profits) for the year. It also stated that RBP had an adjusted operating margin of 54.5%, more than double Reckitt's average.

264. The FY14 Release provided additional commentary on RBP, which had been demerged in December 2014, stating in pertinent part:

Net income (adjusted) attributable to RBP for 2014 was £278m, a decrease of -20% (-16% constant). This was driven by net revenue growth of -8% at constant rates (Q4: -9%) *with strong volume market growth in the US offset by some share decline and pricing. Operating margins were 54.5%[]*, a decline of -640bps due primarily to the decline in net revenue, and continued investment in both the pipeline and the clinical sales force.

265. Also on February 11, 2015, Reckitt hosted a conference call with analysts and investors led by Kapoor and Hennah. In his prepared remarks, Hennah presented on the financial information provided in the FY14 Release, which included the revenue, net income and earnings from the sale of Suboxone Film and a discussion of relevant market conditions. He also stated that RBP, now Indivior, had “GBP1.4 billion of net income in half 2, GBP1.6 billion in the full year. . . . The GBP1.4 billion net income in half 2 comprises both the trading performance of Indivior up to December 23, 2014, and the gain arising on demerger. Revenue and profit progressed in line with expectations.”

E. The 2014 Annual Report Released on March 19, 2015

266. On March 19, 2015, Reckitt issued its 2014 Annual Report, which contained the financial information provided in the FY14 Release, including the revenue, net income and earnings from the sale of Suboxone Film and a discussion of relevant market conditions. The 2014 Annual Report had a section entitled “Realising value from RB Pharmaceuticals (RBP),” which claimed that Reckitt shareholders had received £1.3 billion in gains from the demerger, mostly from the value of RBP’s Suboxone franchise. The Annual Report stated in pertinent part as follows:

Prior to demerger, Indivior PLC was managed as RBP, an independent, global, specialty pharmaceutical business, with its own management team focused solely on addiction treatment and the co-morbidities of addiction. *It was the Board’s view that a stand-alone business will be best placed to create value for Shareholders as it manages the challenges and seizes the opportunities within the field of addiction.* We also believed that Indivior PLC would be a more attractive partner for business development opportunities as a stand- alone and separately managed entity.

Similarly, we believed RB Shareholders would benefit from the single-minded focus of top management on its core businesses in the Health, Hygiene and Home sectors.

Adjusted net income attributable to RBP in 2014 was £278m, a decrease of -20% (-16% at constant exchange rates). This was driven by a net revenue decline of -8% at constant rates with strong volume market growth in the US offset by some share decline and pricing. Operating margins were 54.5%[], a decline of -640bps[] due primarily to the decline in net revenue, and continued investment in both the pipeline and the clinical sales force. Additionally, a gain on demerger of £1,282m has been recognised.

267. Kapoor was quoted in the 2014 Annual Report as stating that Reckitt had “delivered on our promise to demerge the pharmaceutical business,” which had “the potential to deliver significant long-term value to Shareholders.”

268. The 2014 Annual Report also stated that Reckitt employed a robust three-step regulatory compliance process overseen by management to ensure that the Company implemented effective internal controls over financial reporting. It described this process as follows:

- **The first line of defence** is provided by management through the controls, policies and routines RB has in place to deal with risks in the day-to-day running of the business. Controls are designed into systems and processes to appropriately mitigate risks at source. *Adequate managerial and supervisory controls* are then overlaid locally to verify compliance and to highlight and promptly address any breakdown in basic controls;
- **The second line of defence** is provided by geographical and functional management oversight structures, such as Areas, Finance, HR, Supply and Category functions. Management here sets policies, provides direction and maintains oversight of the first line; and
- **The third line of defence** is provided independently by internal and external audit teams, who challenge and report on the accuracy and adequacy of assurance provided by the first and second lines.

269. The 2014 Annual Report also highlighted Reckitt’s purported internal controls, reporting and risk oversight as reasons that investors could take comfort that the Company was adhering to applicable legal requirements and accurately reporting all material risks to investors. It stated in pertinent part as follows:

- **Risk management** – as part of the ongoing risk and control process, operating units review and evaluate risks to the achievement of business objectives and the Board reviews those significant risks which might impact on the achievement of corporate objectives. Mitigating controls, together with any necessary actions, are identified and implemented. A summary of the most significant risks faced by RB is included in the Strategic Report on pages 24 to 27 and full details of RB's relationships and Principal Operating Risks are set out on pages 126 to 132;
- **Operating unit controls** – each operating unit maintains a system of internal control and risk management which is appropriate to its own business environment. Such controls must be in accordance with Group policies and include management authorisation processes, to ensure that all commitments on behalf of RB are entered into only after appropriate approval. In particular, there is a structured process for the appraisal and authorisation of all material capital projects;
- **Compliance controls** – the Group maintains a compliance control programme that includes an independent and anonymous whistleblower reporting system, systematic reviews by the internal audit function, annual management reviews and personal compliance certification as well as specialised training in specific areas and functions of the business. Management provides the Board with regular updates on the compliance controls of the Group and considers recommendations for continuous improvement; and
- **Monitoring** – the effectiveness of the system of internal control and risk management is monitored regularly through a combination of management review, self-assessment, independent review through quality assurance, environment, health & safety and regulatory audits, as well as independent internal and external audit. The results of internal and external audit reviews are reported to and considered by the Audit Committee, and actions are taken to address any significant control matters identified. The Audit Committee also approves annual internal audit plans and is responsible for performing the ongoing review of the system of internal control and risk management on behalf of the Board.

270. The Individual Defendants, other than Thaxter, reviewed and approved the 2014 Annual Report, which quoted Kapoor and Bellamy at length, and thus were responsible for its contents. In addition, the 2014 Annual Report was signed by Kapoor and Bellamy, who certified that the information contained therein was prepared in accordance with international accounting

standards and fairly presented the risks and uncertainties facing the Company, among other information.

271. In addition to the reasons explained above, the statements referenced in ¶¶222-270 were materially false and/or misleading when made because Defendants falsely attributed the success of Suboxone Film to the Film's purported safety rather than to Defendants' fraudulent scheme to mislead the market concerning the Film's safety and to coerce patients and physicians to switch to Film. Defendants knew, or recklessly disregarded, these undisclosed facts.

272. In addition to the reasons explained above, the statements referenced in ¶¶222-270 were materially false and/or misleading when made because they failed to disclose the following adverse facts pertaining to Reckitt's business, operations, and financial condition, which were known to or recklessly disregarded by Defendants:

(a) Defendants had engaged in a scheme to artificially inflate the sales of Suboxone Film by approximately \$3 billion by falsely touting the drug's purportedly superior efficacy and safety as compared to Suboxone Tablets;

(b) contrary to Defendants' public statements, the FDA and Reckitt executives and employees had concluded that Suboxone Film posed a greater risk of abuse and child endangerment than Suboxone Tablets;

(c) Defendants had fabricated a safety scare involving Suboxone Tablets in order to unlawfully delay and prevent generic competition;

(d) Defendants had engaged in a massive marketing campaign that had misrepresented the purported benefits of Suboxone Film as compared to Suboxone Tablets to doctors, healthcare providers, government regulators and investors;

(e) Defendants had encouraged Suboxone sales through medical providers that they knew were overprescribing the drug, facilitating the drug's abuse and/or prescribing it in a careless and clinically unwarranted manner, often to hundreds of individuals at a time;

(f) Defendants engaged in anticompetitive practices that coerced patients and physicians to use Suboxone Film over Suboxone Tablets to protect Reckitt's market share of Suboxone;

(g) Defendants falsified data concerning Suboxone Film to persuade MassHealth to make the Film a preferred drug on the MassHealth formulary;

(h) Reckitt lacked effective compliance controls concerning the marketing of Suboxone Film;

(i) as a result of (a)-(h) above, Reckitt's revenues, net income, and earnings were artificially inflated and the product of illicit business practices; and

(j) as a result of (a)-(h) above, Reckitt and RBP were exposed to extraordinary undisclosed legal and reputational risks that could result in billions of dollars in fines, lost business, and legal judgments or other monetary penalties.

273. Even after the demerger of RBP, Defendants continued to conceal the truth from investors regarding the true risks and benefits of Suboxone Film.

274. Meanwhile, Indivior continued to propagate the false basis on which it discontinued Suboxone Tablets from the market, and to tout the "additional safety and compliance features" of Suboxone Film. In its 2016 Form 20-F, filed with the SEC on July 14, 2016, Indivior stated as follows:

We announced that we were discontinuing distribution of SUBOXONE® Tablet in the U.S. market in September 2012 *owing to pediatric safety concerns*. In order to ensure continuity in patient treatment, and to provide adequate time for consultation

with regulatory bodies and treatment stakeholders, withdrawal did not occur until March 2013. . . .

SUBOXONE® Film was developed as an alternative to the sublingual tablet with the intention of producing similar safety and efficacy to SUBOXONE® Tablet, but *with additional safety and compliance features*.

THE TRUTH BEGINS TO EMERGE

A. **Reckitt Stuns Investors by Reporting Hundreds of Millions in Charges in Connection with Suboxone and the DOJ Investigation**

275. The truth began to emerge on July 24, 2017, when Reckitt announced, in connection with its second quarter 2017 financial results, that it had recorded a £318 million charge related to ongoing DOJ and FTC investigations into its former RBP operations. On this news, the price of Reckitt ADSs dropped 5% and Reckitt ordinary shares dropped 3.3%.

276. Reckitt's disclosure of a £318 million charge surprised and disappointed securities analysts covering the Company. A Credit Suisse analyst wrote, "The £318m provision related to RB Pharma (Indivior) wasn't expected[.]" Likewise, a Kepler Cheuvreux analyst wrote, "On the negative side, [Reckitt] reported an unexpected one-off of GBP318m related to Indivior." Analysts at Investec wrote:

Combined with a new provision of £318m related to the Indivior spin, we regard the statement as disappointing. Sell. . . . While there are no additional provisions for the Korean Humidifier Sanitiser issue, a sizeable £318m charge against potential payments relating to the Indivior spinoff in December 2014 has been taken. Details have not been disclosed by the company.

277. However, because Defendants failed to disclose the truth about their fraudulent scheme to artificially inflate sales of Suboxone Film through fraud and misrepresentation, the price of Reckitt Securities remained artificially inflated.

278. On February 19, 2018, Reckitt announced, in connection with its full-year 2017 financial results, that it had recorded an exceptional charge of £296 million due to the investigations, and that the investigation now also involved the California Department of

Insurance. On this news, the price of Reckitt ADSs declined more than 10% and Reckitt ordinary shares dropped 7.5%. However, because Defendants failed to disclose the truth about their fraudulent scheme to artificially inflate sales of Suboxone Film through fraud and misrepresentation, the price of Reckitt ADSs remained artificially inflated.

B. The DOJ’s Criminal Indictment of the Former RBP

279. On April 9, 2019, the DOJ filed a criminal indictment against RBP (now Indivior), which detailed a years-long scheme involving the marketing and sale of Suboxone Film that had generated more than \$3 billion in illicit proceeds. The 28-count criminal indictment charged Indivior with a multitude of felonies, including conspiracy and mail, wire, and healthcare fraud. The Indictment quoted damning emails and other documents that implicated Reckitt and RBP senior management in the fraudulent scheme, including many of the Individual Defendants and other C-suite executives described herein. On this news, the price of Reckitt ADSs declined more than 6% and Reckitt ordinary shares dropped 6.5%.

C. After the Class Period, Reckitt and RBP/Indivior Settle Claims with the DOJ and the FTC, and Thaxter, Baxter, and Indivior Solutions Plead Guilty to Federal Crimes

280. On July 11, 2019, Reckitt agreed to settle the federal investigations into its marketing and sale of Suboxone Film for \$1.4 billion. The DOJ called the settlement the “largest opioid settlement in US history.”

281. In the Non-Prosecution Agreement entered into between the DOJ and Reckitt, the DOJ contended that it had certain civil claims against Reckitt for engaging in the following conduct between January 1, 2010, and December 31, 2014, stating as follows:

(a) The United States contends that RB Group¹⁵ directly or through its subsidiaries knowingly promoted the sale and use of Suboxone to physicians who were writing

¹⁵ “RB Group” was defined in the Non-Prosecution Agreement as Reckitt Benckiser Group plc and Reckitt Benckiser LLC, formerly d/b/a Reckitt Benckiser Inc., collectively.

prescriptions (a) without any counseling or psychosocial support, such that the prescriptions were not for a medically accepted indication; and (b) for uses that were unsafe, ineffective, and medically unnecessary and that were often diverted for uses that lacked a legitimate medical purpose. Such prescriptions lacking a legitimate medical purpose are also not for a medically accepted indication.

(b) The United States contends that RB Group directly or through its subsidiaries knowingly promoted the sale or use of Suboxone Film using false and misleading claims that Suboxone Film was less subject to diversion and abuse than other buprenorphine products and that Suboxone Film was less susceptible to accidental pediatric exposure than Suboxone Tablets. Physicians relied on these false and misleading claims in prescribing Suboxone Film, and state Medicaid agencies relied on these false and misleading claims to their detriment in making formulary and prior authorization decisions.

(c) The United States contends that RB Group directly or through its subsidiaries knowingly submitted a petition to the Food and Drug Administration on September 25, 2012, fraudulently claiming that Suboxone Tablet had been discontinued “due to safety concerns” about the tablet formulation of the drug and took other steps to fraudulently delay the entry of generic competition for Suboxone in order to improperly control pricing of Suboxone, including pricing to federal healthcare programs.

282. On the same day the settlement was announced, the FTC filed its complaint against Reckitt itself for monopolization of the Suboxone market. Reckitt’s \$1.4 billion settlement included a payment of \$50 million to the FTC to settle the monopolization claim. *See* Ex. B.

283. In its complaint, the FTC accused Reckitt of willfully maintaining its monopoly power as to Suboxone by promoting the sale or use of Suboxone Film using false and misleading claims that the Film was less susceptible to accidental pediatric exposure than the Tablets. According to the FTC, these misrepresentations coerced a majority of consumers to switch to the more expensive Suboxone Film before the entry of lower-cost generic Suboxone Tablets, thereby preserving the lucrative Suboxone monopoly and harming consumers. The FTC alleged that Reckitt’s conduct had the purpose and effect of wrongfully impeding and suppressing lower-cost generic competition to Suboxone Tablets by eliminating the most cost-efficient means of competing.

284. The FTC alleged that Reckitt's use of coercive and exclusionary conduct to convert patients from Suboxone Tablets to Suboxone Film largely foreclosed generic competitors from the most cost-effective means of competing. By the time generic Suboxone Tablets were able to enter the market, 85% of Suboxone prescriptions were being written for the film version of Suboxone. This resulted in significant consumer harm by denying the majority of consumers and other purchasers of Suboxone meaningful access to lower-cost therapeutically equivalent versions of Suboxone.

285. In its complaint against Reckitt, the FTC brought one count of Monopolization. The FTC alleged that Reckitt's willful maintenance of its monopoly through a course of anticompetitive conduct, including forcing the market to convert from Suboxone Tablets to Suboxone Film based on, *inter alia*, knowingly false claims related to patient safety, and submitting a meritless citizen petition to the FDA, constitutes an unfair method of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. §45(a). According to the FTC, this conduct had the purpose and effect of wrongfully impeding and suppressing lower-cost generic competition to Suboxone Tablets by eliminating the most cost efficient means of competing.

286. On November 7, 2019, the FDA revoked, as improperly granted, Indivior's orphan-drug designation for buprenorphine for treatment of opiate addiction in opiate users pursuant to 21 CFR §316.29(a)(3). After a review of a citizen petition from another biopharmaceutical company challenging buprenorphine's orphan-drug designation, as well as RBP's original request in 1993 for orphan-drug designation, the FDA determined that the original request for orphan-drug designation failed to establish that there was no reasonable expectation that the costs of developing a buprenorphine drug to treat opiate use disorder would be recovered from the sales of such a drug in the U.S.

287. Although the FDA did not find that Reckitt had defrauded the FDA when it originally sought orphan-drug status, it did find that Reckitt's plan regarding the marketing of buprenorphine for opioid use disorder was to obtain orphan-drug designation, change the laws to increase the size of the market, and obtain marketing approval. The FDA found that Reckitt's Board of Directors "appears to have decided, at the time of the designation request, to approve the development plan based on the possibility that Indivior [then known as RBP] could accomplish those goals." The FDA added:

Based on the events described, it seems clear that Indivior would not have sought orphan-drug designation and marketing approval for buprenorphine for treatment of [opioid use disorder] unless it also had a reasonable expectation of expanding the market for buprenorphine. Although a change in the law was far from assured, Indivior's Board seems to have believed that there was a reasonable expectation that such a change would occur.

288. On June 30, 2020, Thaxter pleaded guilty to a one-count Information charging him with causing the "misbranded opioid drug Suboxone Film" to be introduced to interstate commerce in violation of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301, particularly in violation of 21 U.S.C. §§331(a), 333(a)(1), and 352(a). As discussed above, despite receiving contrary data, Thaxter, in his oversight of RBP's efforts to gain MassHealth coverage for the Film, caused or failed to prevent RBP from providing false and misleading safety statistics, and failed to correct the information for approximately three years. On October 22, 2020, he was sentenced to six months in federal prison, one year of supervised release, and ordered to pay a fine of \$100,000 and forfeit \$500,000. According to the U.S. Attorney's Office prosecuting Thaxter, it is extremely rare for a pharmaceutical executive to be sent to prison. In sentencing Thaxter to prison, U.S. District Judge James P. Jones stated, "[T]here's no doubt the fact is that a serious and intentional misrepresentation occurred in the marketing of [Thaxter's] company's premier product, which he admits he failed to prevent."

289. On August 31, 2020, Baxter pleaded guilty to a one-count Information nearly identical to Thaxter's, for the violation of 21 U.S.C. §§331(a), 333(a)(1), and 352(a) for causing "the introduction and delivery for introduction into interstate commerce of Suboxone Film, a drug that was misbranded in that the drug's labeling was false and misleading." Baxter was in a similar oversight role for the efforts to win preferred-drug status for the Film and also allowed misleading information to be sent to MassHealth, despite receiving contradictory information, and failed to correct it. On December 17, 2020, Baxter was sentenced to six months of home detention, 100 hours of community service, and a \$100,000 criminal fine. During his allocution, Baxter stated, "Whilst I was not in a position to supervise sale, on the occasions when I was alerted to potentially troubling conduct on the sales side, I elevated them to members of our management with the relevant responsibility."

290. On July 24, 2020, the Indivior entities agreed to pay \$600 million to resolve criminal and civil liability associated with the marketing of Suboxone. Indivior Solutions pleaded guilty to a one-count felony Information, detailing the same events pertaining to Thaxter's and Baxter's criminal liability, and charging false statements relating to healthcare matters in violation of 18 U.S.C. §1035. Indivior Solutions admitted to "knowingly and willingly" making false statements relating to the pediatric safety of the Film, and that it "failed to correct its inaccurate, false, and misleading statements" made to MassHealth. Indivior Solutions was sentenced to pay \$289 million in criminal penalties on November 12, 2020.

291. Also on July 24, 2020, Indivior entered into civil settlement agreements with the DOJ and FTC. Indivior agreed to pay the United States and certain participating states \$300 million to resolve allegations related to the Indivior companies' efforts to promote and increase sales of the Film, including the citizen's petition to the FDA, from 2010 through 2015. Indivior

also entered into a \$10 million civil settlement with the FTC, resolving claims that it engaged in illegal monopolization and anticompetitive conduct in blocking generic competition to Suboxone. As part of a consent decree, Indivior agreed that it would notify the FTC if it filed a citizen petition with the FDA in connection with a drug product, and that it would simultaneously disclose all studies and data relevant to that citizen petition to both the FDA and FTC. Indivior further agreed not to withdraw a drug from the market or otherwise disadvantage a drug after obtaining approval to market another drug containing the same active ingredient.

292. In addition to the criminal and civil resolutions, Indivior executed a five-year Corporate Integrity Agreement with the Department of Health and Human Services Office of Inspector General. The agreement requires Indivior to implement numerous accountability and auditing provisions, including certifying compliance, conducting risk assessments and other monitoring, and allowing an independent review organization to conduct audits, all on an annual basis. According to the U.S. Attorney's Office prosecuting Indivior, these are unprecedented terms for a government resolution with a pharmaceutical company.

D. Reckitt Seeks Indemnification from Indivior for \$1.4 Billion

293. On November 13, 2020, Reckitt filed a claim in the Commercial Court, High Court of Justice of England and Wales to preserve its right to seek indemnification under the 2014 demerger agreement. The amount claimed under the submission was £1,073,622,580.51, or approximately \$1.4 billion – the amount Reckitt paid to the U.S. government to resolve its own potential criminal and civil liability.

294. On January 25, 2021, Indivior agreed to pay Reckitt \$50 million to settle Reckitt's claim seeking indemnity under the demerger agreement. According to a press release issued by Indivior, pursuant to the settlement, Reckitt agreed to withdraw the \$1.4 billion claim and to release Indivior from any claim for indemnity under the demerger agreement relating to the DOJ and FTC

settlements that Reckitt entered into in July 2019, as well as other claims for indemnity arising from those matters. In turn, Indivior agreed to pay Reckitt \$50 million over the next five years. Indivior also agreed to release Reckitt from any claims to seek damages relating to its settlement with the DOJ and the FTC.

295. As a result of Defendants' wrongful acts and omissions, Plaintiffs and the Class purchased Reckitt Securities at artificially inflated prices and suffered significant losses when the relevant truth was revealed in part over time.

**DEFENDANTS VIOLATED ITEM 303 BY FAILING TO DISCLOSE
THAT THE FRAUDULENT SUBOXONE SCHEME
SUBJECTED RECKITT TO MONETARY RISKS**

296. Pursuant to Item 303 of U.S. Securities and Exchange Commission ("SEC") Regulation S-K, 17 C.F.R. §229.30 ("Item 303") and the SEC's related interpretive releases thereto, an issuer is required to disclose known trends, uncertainties or risks that have had, or are reasonably likely to have, a materially adverse impact on net sales or revenues, or income from continuing operations. Such disclosure is required by an issuer in regulatory reports.

297. The SEC issued an interpretive release on Item 303 on or about May 18, 1989, stating:

Required disclosure is based on currently known trends, events, and uncertainties that are reasonably expected to have material effects, such as: A reduction in the registrant's product prices; erosion in the registrant's market share; changes in insurance coverage; or the likely non-renewal of a material contract.

* * *

A disclosure duty exists where a trend, demand, commitment, event or uncertainty is both presently known to management and reasonably likely to have material effects on the registrant's financial condition or results of operation.

298. Item 303 required Reckitt's regulatory filings to describe "any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable

or unfavorable impact on net sales or revenues or income from continuing operations.” 17 C.F.R. §229.303(a)(3)(ii). Similarly, Item 303 required Reckitt’s regulatory reports to disclose events that Reckitt knew would “cause a material change in the relationship between costs and revenues” and “any unusual or infrequent events or transactions or any significant economic changes that materially affected the amount of reported income from continuing operations and, in each case, indicate the extent to which income was so affected.” 17 C.F.R. §229.303(a)(3)(i), (ii).

299. Reckitt was required to disclose the impact and/or potential liabilities associated with its fraudulent scheme to boost sales of Suboxone Film on its reported revenues and that this fraudulent scheme subjected it to monetary and reputational risks. Defendants had a duty prior to July 24, 2017 to disclose that Reckitt’s fraudulent and anticompetitive conduct subjected it to monetary risks of criminal and/or civil governmental prosecution. As alleged herein, Defendants knew that they and other Reckitt employees had committed fraudulent acts well before Reckitt disclosed it had recorded a £318 million charge related to ongoing DOJ and FTC investigations into its former RBP operations on July 24, 2017.

300. In addition, Defendants knew that Reckitt was under investigation by multiple governmental entities. In 2011, RBP received a subpoena from the U.S. Attorney for the District of New Jersey relating to the promotion, marketing, and sale of Suboxone Film. In late 2012, the FTC and the Attorney General of New York commenced non-public investigations of Reckitt, RBP, and other Reckitt entities concerning Suboxone Film. In December 2013, the U.S. Attorney for the Western District of Virginia executed a search warrant on RBP’s headquarters in Richmond and conducted searches of the homes of four field-based employees.

ADDITIONAL SCIENTER ALLEGATIONS

301. As alleged herein, Defendants acted with scienter in that they knew the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents and in actions intended to manipulate the market price of Reckitt Securities as primary violations of the securities laws.

302. As set forth elsewhere herein in detail, Defendants, by virtue of their receipt of information reflecting the true facts regarding Reckitt, their control over, and/or receipt or modification of, Reckitt's allegedly materially misleading misstatements, and/or their associations with the Company that made them privy to confidential proprietary information concerning Reckitt, participated in the fraudulent scheme alleged herein. The adverse developments at issue also impacted the Company's most important revenue streams and directly involved the Company's most senior executives, including the Individual Defendants, as detailed herein.

303. The Individual Defendants also received millions of dollars in performance compensation, bonuses and other remuneration for their role in the fraudulent scheme. While they respectively held the title of Reckitt CEO, Becht and Defendant Kapoor were among the highest-paid corporate executives in the United Kingdom. Becht, as CEO of Reckitt from 1995-2011, was paid more than £230 million. In 2010 alone, Becht received compensation totaling £90 million. Kapoor, as CEO of Reckitt from 2011-2019, was paid more than £101 million.

304. The suspicious timing of stock sales by Becht and Day, Reckitt's then-CFO, further demonstrate their consciousness of wrongdoing. Becht and Day collectively sold more than 5,287,718 shares of their personally held Reckitt stock for gross proceeds of more than

£171,562,233 (or \$257,343,350 in U.S. Dollars) while Reckitt was engaged in private communications with the FDA about the safety of the Film. The exchange of letters culminated in a letter sent by the FDA on March 29, 2010 denying Reckitt's pediatric safety claims. Stock sales by Becht and Day during this nine-month time period, including the three months following Reckitt's receipt of the FDA's response letter (October 5, 2009 through June 30, 2010), are as follows:

Insider	Title	Date	Number of Shares	Proceeds
Bart Becht	Chief Executive Officer	11/26/09	342,931	£10,511,281
Bart Becht	Chief Executive Officer	11/27/09	519,796	£15,846,033
Bart Becht	Chief Executive Officer	11/30/09	238,611	£7,229,794
Bart Becht	Chief Executive Officer	12/1/09	280,000	£8,678,152
Bart Becht	Chief Executive Officer	12/2/09	265,906	£8,254,334
Bart Becht	Chief Executive Officer	12/4/09	587,364	£18,336,447
Bart Becht	Chief Executive Officer	3/1/10	500,000	£17,089,850
Bart Becht	Chief Executive Officer	3/8/10	500,000	£17,182,700
Bart Becht	Chief Executive Officer	3/15/10	500,000	£17,256,050
Bart Becht	Chief Executive Officer	3/15/10	50,000	£1,725,605
Bart Becht	Chief Executive Officer	3/16/10	50,000	£1,712,405
Bart Becht	Chief Executive Officer	3/18/10	50,000	£1,718,270
Bart Becht	Chief Executive Officer	3/19/10	50,000	£1,741,730
Bart Becht	Chief Executive Officer	3/22/10	50,000	£1,748,570
Bart Becht	Chief Executive Officer	3/23/10	50,000	£1,754,435

Insider	Title	Date	Number of Shares	Proceeds
Bart Becht	Chief Executive Officer	3/24/10	50,000	£1,746,615
Bart Becht	Chief Executive Officer	3/25/10	50,000	£1,766,165
Bart Becht	Chief Executive Officer	3/26/10	50,000	£1,770,075
Bart Becht	Chief Executive Officer	5/27/10	150,000	£4,739,910
Bart Becht	Chief Executive Officer	5/27/10	179,406	£5,699,122
Bart Becht	Chief Executive Officer	5/28/10	20,594	£653,174
Bart Becht	Chief Executive Officer	6/2/10	200,000	£6,341,380
Bart Becht	Chief Executive Officer	6/14/10	50,260	£1,611,763
Becht Total:			4,784,868	£155,083,860
Colin Day	Chief Financial Officer	11/25/09	60,000	£1,885,992
Colin Day	Chief Financial Officer	12/1/09	80,000	£2,479,472
Colin Day	Chief Financial Officer	12/10/09	20,000	£623,778
Colin Day	Chief Financial Officer	3/17/10	32,850	£1,117,347
Colin Day	Chief Financial Officer	3/18/10	160,000	£5,498,464
Colin Day	Chief Financial Officer	6/17/10	150,000	£4,873,320
Day Total:			502,850	£16,478,373
Combined Total:			5,287,718	£171,562,233¹⁶

¹⁶ \$257,343,350 in U.S. Dollars as of June 2010, using a British Pound to U.S. Dollar exchange rate of 1.50.

305. By comparison, during the nine months preceding October 5, 2009, Becht only made one sale, of 164,247 shares of Reckitt stock, for proceeds of £4,242,944. Day only made two sales, totaling 192,850 shares, for proceeds of £5,205,468.

306. Defendants were further motivated to engage in a fraudulent course of conduct in order to find a new source of profitability for Suboxone before generic versions of Suboxone Tablets entered the market.

307. Defendants were further motivated to engage in a fraudulent course of conduct in order to artificially inflate the value of RBP before demerging it.

308. In addition, in 2011, the U.K.'s Office of Fair Trading ("OFT") found that Reckitt engaged in a similar product-hop scheme by abusing its dominant position in the market for the supply of alginates and antacids in the U.K.'s National Health Service ("NHS") prescription channel. The OFT alleged that Reckitt, having foreseen generic competition for its dominant branded antacid, Gaviscon Original Liquid ("GL"), withdrew the supply of prescription packs to pharmacists in 2005 after the product's patent had expired but before the publication of the generic name for it, so that more prescriptions would be issued for its alternative product, Gaviscon Advance Liquid, which was patent-protected. Therefore, pharmacies that received prescriptions for Gaviscon Advance Liquid had to dispense it because there were no generic alternatives.

309. According to the OFT, the withdrawal took place in the context of a "long term intention to delay the onset of full generic competition," and internal documents indicated that, over a number of years, Reckitt had been considering actions that would delay or inhibit the introduction of generics. Reckitt's internal documents also revealed that it actively considered its ability to persuade doctors and patients to switch to Gaviscon Advance Liquid, the patent-protected product. Notably, as detailed in "Project Atlas," Reckitt attempted an alternative plan, "the

development of a patented Gaviscon Liquid variant that is essentially similar to current Gaviscon Liquid but differs somehow from the monograph that is currently being developed by the British Pharmacopoeia Committee for current Gaviscon Liquid,” with the objective to “replace/cannibalise all current 500ml Gaviscon Liquid sales (Peppermint and Aniseed) in the NHS with the new patent protected variant.” Internal documents listed as a requirement for success: “that the replacement is perceived as being an improvement on GL[.]” Ultimately, Reckitt did not implement the plan because it failed to successfully develop a suitable new formulation. The OFT found that Reckitt’s Board of Directors, which included Defendant Bellamy, and Executive Committee were involved in the decision-making process relevant to the Gaviscon product-hop scheme.

310. As such, the Individual Defendants knew, or were reckless in not knowing, of the undisclosed facts detailed herein.

LOSS CAUSATION/ECONOMIC LOSS

311. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Reckitt Securities and operated as a fraud or deceit on purchasers of Reckitt Securities. When the truth about Reckitt’s misconduct was revealed over time, the value of Reckitt Securities declined significantly as the prior artificial inflation no longer propped up Reckitt Securities’ price.

312. The declines in the price of Reckitt Securities were the direct result of the nature and extent of Defendants’ fraud finally being revealed to investors and the market. The timing and magnitude of the price declines negate any inference that the losses suffered by Plaintiffs and other members of the Class were caused by changed market conditions, macroeconomic or industry factors or company-specific facts unrelated to Defendants’ fraudulent conduct.

313. The economic loss, *i.e.*, damages, suffered by Plaintiffs and other Class members was a direct result of Defendants' fraudulent scheme to artificially inflate the price of Reckitt Securities and the subsequent significant decline in the value of Reckitt Securities when Defendants' prior misrepresentations and other fraudulent conduct were revealed.

314. At all relevant times, Defendants' materially false and misleading statements or omissions alleged herein directly or proximately caused the damages suffered by Plaintiffs and other Class members. Those statements were materially false and misleading through their failure to disclose a true and accurate picture of Reckitt's business, operations and financial condition, as alleged herein. Throughout the Class Period, Defendants issued materially false and misleading statements and omitted material facts necessary to make Defendants' statements not false or misleading, causing the price of Reckitt Securities to be artificially inflated. Plaintiffs and other Class members purchased Reckitt Securities at those artificially inflated prices, causing them to suffer damages as complained of herein when the relevant truth was revealed.

**APPLICABILITY OF PRESUMPTION OF RELIANCE:
FRAUD-ON-THE-MARKET DOCTRINE**

315. Plaintiffs and the other members of the Class will rely, in part, upon the presumption of reliance established by the fraud-on-the-market presumption of reliance in that, among other things:

- (a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- (b) the omissions and misrepresentations were material;
- (c) Reckitt Securities traded in an efficient market;
- (d) the misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of Reckitt Securities; and

(e) Plaintiffs and the other members of the Class purchased Reckitt Securities between the time Defendants misrepresented or failed to disclose material facts and the time the true facts began to be disclosed, without knowledge of the misrepresented or omitted facts.

316. At all relevant times, the market for Reckitt Securities was an efficient market for the following reasons, among others:

(a) Reckitt met the requirements for listing, and was listed and actively traded on the London Stock Exchange, an efficient and automated market, in the form of ordinary shares, and on the OTC Market, an efficient market, in the form of ADSs;

(b) Reckitt ADSs were sponsored by the Company and represented Reckitt ordinary shares, which were listed and actively traded on the London Stock Exchange, a highly efficient and automated market;

(c) According to the Company's 2018 Annual Report, there were more than 736 million Reckitt shares issued and outstanding, held by more than 17,000 nominees, individuals and institutional investors, representing a very broad and active trading market;

(d) Reckitt regularly communicated with public investors via established market communication mechanisms, including the regular dissemination of press releases on national circuits of major newswire services, the Internet, and other wide-ranging public disclosures;

(e) Reckitt filed periodic public reports with United Kingdom securities regulators;

(f) Reckitt was followed by securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of their

respective brokerage firms. Each of these reports was publicly available and entered the public marketplace; and

(g) Unexpected material news about Reckitt was rapidly reflected in and incorporated into Reckitt Securities prices during the Class Period.

317. Because Reckitt is a publicly traded company, Defendants knew, understood, and had reason to expect that: (1) their misstatements would artificially inflate the price of Reckitt Securities; (2) investors would rely on the price of Reckitt Securities as reflecting accurate information known to Reckitt and its principals; and (3) their misstatements and omissions would induce Plaintiffs and/or their agents and other Class members to purchase Reckitt Securities during the Class Period.

318. As a result of the foregoing, the market for Reckitt Securities promptly digested current information regarding the Company from all publicly available sources and reflected such information in the price of Reckitt Securities. Under these circumstances, all purchasers of Reckitt Securities during the Class Period suffered similar injury through their purchase of Reckitt Securities at artificially inflated prices, and a presumption of reliance applies.

319. Further, Plaintiffs' and other Class members' reliance will be proved on a Class-wide basis through common, circumstantial evidence that Plaintiffs would not have purchased Reckitt Securities but for Defendants' uniform misrepresentations and omissions about Reckitt's Suboxone drugs, business, operations, and financial condition.

320. Plaintiffs are also entitled to a presumption of reliance under *Affiliated Ute Citizens v. United States*, 406 U.S. 128 (1972), because the claims asserted herein are predicated in part upon omissions of material fact for which there was a duty to disclose. Specifically, Plaintiffs are

entitled to a presumption of reliance throughout the Class Period because, as more fully alleged above, Defendants failed to disclose material information regarding Suboxone.

NO SAFE HARBOR

321. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the false statements alleged. Many of the statements herein were not identified as “forward-looking statements” when made. Alternatively, to the extent that there were any forward-looking statements, no meaningful cautionary language identified important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. If the statutory safe harbor indeed applies to any forward-looking statements pleaded herein, Defendants are liable because at the time each forward-looking statement was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward looking statement was authorized and/or approved by an executive officer of the Company who knew that those statements were false when made.

CLASS ACTION ALLEGATIONS

322. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of: (i) all persons who purchased Reckitt ADSs on the OTC Market in the United States and/or incurred irrevocable liability for the ADSs in the United States and/or to whom title to the ADSs passed in the United States, during the Class Period; and (ii) all persons who purchased Reckitt ordinary shares during the Class Period (collectively, the “Class”). Excluded from the Class are Defendants and their families, Reckitt, the officers and directors of Reckitt, at all relevant times, members of their immediate families, and their legal representatives, heirs, successors or assigns and any entity in which Defendants and/or Reckitt have or had a controlling interest.

323. Common questions of law and fact predominate and include: (a) whether Defendants violated the Exchange Act; (b) whether Defendants violated U.K. statutory and/or English common law; (c) whether Defendants omitted and/or misrepresented material facts; (d) whether Defendants knew or recklessly disregarded that their statements were false; (e) whether the price of Reckitt Securities was artificially inflated during the Class Period; and (f) the extent of and appropriate measure of damages.

324. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Reckitt ADSs were actively traded on the OTC Market and Reckitt ordinary shares were actively traded on the London Stock Exchange. Upon information and belief, these shares are held by thousands of geographically dispersed individuals.

325. Plaintiffs' claims are typical of those of the Class. Prosecution of individual actions would create a risk of inconsistent adjudications. Plaintiffs will adequately protect the interests of the Class. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

COUNT I

For Violations of §10(b) of the Exchange Act and Rule 10b-5 Against All Defendants on Behalf of ADS Purchasers

326. Birmingham and Sterling Heights repeat and reallege the above allegations as if fully set forth herein.

327. During the Class Period, Defendants disseminated or approved false statements, which they knew or recklessly disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

328. Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 in that they:

- (a) employed devices, schemes and artifices to defraud;
- (b) made untrue statements of material fact or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or
- (c) engaged in acts, practices and a course of business that operated as a fraud or deceit upon Birmingham, Sterling Heights, and others similarly situated in connection with their purchases of Reckitt ADSs during the Class Period.

329. Birmingham, Sterling Heights and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Reckitt ADSs and suffered losses when the relevant truth was disclosed. Birmingham, Sterling Heights, and the Class would not have purchased Reckitt ADSs at the prices they paid, or at all, if they had been aware that the market price had been artificially and falsely inflated by Defendants' misleading statements.

COUNT II

For Violations of §20(a) of the Exchange Act Against the Individual Defendants on Behalf of ADS Purchasers

330. Birmingham and Sterling Heights repeat and reallege the above allegations as if fully set forth herein.

331. The Individual Defendants acted as controlling persons of Reckitt within the meaning of Section 20(a) of the Exchange Act. By reason of their positions as officers and directors of Reckitt, and their ownership of Reckitt Securities, the Individual Defendants had the power and authority to, and did, cause Reckitt to engage in the wrongful conduct complained of herein.

332. By reason of such conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act.

333. As a direct and proximate result of the Individual Defendants' wrongful conduct, Birmingham, Sterling Heights and the other Class members suffered damages in connection with their purchases of Reckitt ADSs during the Class Period.

COUNT III

For Violations of English Common Law Fraudulent Misrepresentation and Deceit Against All Defendants on Behalf of Reckitt Ordinary Share Purchasers

334. Pontiac repeats and realleges each and every allegation in the foregoing paragraphs as if fully set forth herein.

335. This Count is asserted against Defendants based on English common law principles of fraudulent misrepresentation (deceit) and conspiracy or common design to commit that fraud, such that each Defendant is liable in deceit and/or is liable as a joint tortfeasor.

336. As alleged herein, Defendants made, expressly and impliedly, material misrepresentations of fact (including by intentionally or recklessly omitting to disclose material facts) to Pontiac and the Class, and failed to correct those misrepresentations, about: the marketing and sale of Suboxone Film; the Company's scheme to mislead both investors and the wider public regarding the health and safety risks of the Film; the existence of coercive and anticompetitive practices; the sustainability of RBP's business and the reasons for RBP's demerger from Reckitt; as well as Reckitt's compliance practices during the Class Period.

337. Defendants also conspired with each other by way of common design for the purpose of misleading Pontiac and the Class regarding the matters summarized in the previous paragraph and each committed overt acts, including, but not limited to, the making of false and misleading statements, in furtherance of such conspiracy and common design.

338. As further alleged herein, the aforesaid misrepresentations and omissions by Defendants were made fraudulently: they were made by Defendants intentionally, knowing the misrepresentations to be false and/or knowingly failing to correct those representations which had subsequently become false; alternatively, the misrepresentations were made by Defendants without belief in their truth; or, in the further alternative they were made by Defendants with recklessness, not caring whether the misrepresentations were true or false, and were made to induce reliance thereon by Pontiac and the Class when deciding to acquire and/or retain Reckitt ordinary shares (or otherwise make investment decisions in relation to those securities) during the Class Period.

339. The aforesaid misrepresentations and omissions by Defendants constitute fraud and deceit under English common law.

340. Pontiac and the Class reasonably relied on Defendants' misrepresentations when deciding to purchase or retain Reckitt ordinary shares and when otherwise making investment decisions with regard to those securities during the Class Period, and did not know of the true position behind any of the misrepresentations and omissions at the time the investment decisions were made. Pontiac's and the Class's reliance was justified since they were unaware of the true facts; if the true facts had been known to Pontiac and the other members of the Class, they would not have acted as they did in purchasing or retaining Reckitt ordinary shares or in otherwise making investment decisions in relation to them.

341. As a direct and proximate cause of the fraud and deceit by Defendants, Pontiac and the Class suffered damages in connection with their investments in Reckitt ordinary shares during the Class Period.

342. The fraud and deceit committed by Defendants was intentional and/or involved acts that recklessly disregarded the rights of others, including Pontiac and the Class. As a result, Defendants are liable to Pontiac and the Class for putative damages.

343. To the extent necessary, it is to be inferred from all the facts and matters set out herein that the aforesaid misrepresentations and omissions (a) were made by Defendants with the intention that Pontiac and the Class rely upon them, and (b) induced Pontiac and the Class to acquire and/or retain Reckitt ordinary shares (or otherwise make investment decisions in relation to those securities) during the Class Period.

COUNT IV

For Violations of the Financial Services and Markets Act of the United Kingdom Against Reckitt on Behalf of Reckitt Ordinary Share Purchasers

344. Pontiac repeats and realleges each and every allegation in the foregoing paragraphs as if fully set forth herein.

345. This Count is brought pursuant to Section 90A of the FSMA, as amended by the Companies Act of 2006 and the FSMA 2000 (Liability of Issuers) Regulations 2010 (2010/1192), and Schedule 10A of the FSMA against Reckitt seeking damages in relation to Pontiac's and the Class's acquisition and/or retention and/or disposal of Reckitt ordinary shares during the Class Period.

346. Reckitt, as an issuer of securities to which Schedule 10A applies, made untrue and/or misleading statements in published information (within the meaning of paragraph 2 of Schedule 10A), including in reports and statements published in response to provisions implementing Articles 4, 5, and 6 of Directive 2004/109/EC of the Transparency Obligations Directive of December 31, 2004, in its preliminary statements pertaining thereto, and as further set

out herein. Further, Reckitt dishonestly omitted to include information which was required to be included in that published information as set out herein.

347. One or more of the Individual Defendants, in discharging their managerial responsibilities on behalf of Reckitt, knew the aforesaid statements were untrue and/or misleading or were reckless as to whether they were untrue and/or misleading, and, further, they knew the aforesaid omissions were dishonest (within the meaning of paragraph 6 of Schedule 10A) concealments of material facts.

348. Pontiac and the Class reasonably relied on the aforesaid untrue and/or misleading statements and omissions when deciding to purchase or retain Reckitt ordinary shares and when otherwise making investment decisions with regard to those ordinary shares, and did not know of the true position behind any of the untrue and/or misleading statements, or of the omissions of material facts, in the published information, at the time the investment decisions were made. Pontiac and the Class's reliance was justified since they were unaware of the true facts; if the true facts had been known to Pontiac and the other members of the Class, they would not have acted as they did in purchasing or retaining Reckitt ordinary shares.

349. To the extent necessary, it is to be inferred from all the facts and matters set out herein that the aforesaid untrue and/or misleading statements and omissions induced Pontiac and the Class to acquire and/or retain Reckitt ordinary shares (or otherwise make investment decisions in relation to those securities) during the Class Period.

350. Pontiac and the Class have suffered loss in respect of Reckitt ordinary shares as a result of the aforesaid untrue and/or misleading statements and omissions.

351. By reason of the foregoing, Reckitt is liable to Pontiac and the Class for compensation as provided by Section 90A of the FSMA 2000, as amended.

COUNT V

For Violations of English Common Law, Negligent Misrepresentation and Misstatement Against All Defendants on Behalf of Reckitt Ordinary Share Purchasers

352. Pontiac repeats and realleges each and every allegation in the foregoing paragraphs as if fully set forth herein.

353. This Count is asserted against Defendants based on English common law principles of negligent misrepresentation and misstatement.

354. As alleged herein, Defendants made, expressly or impliedly, material misrepresentations (including by omitting to disclose material facts) to Pontiac and the Class and failed to correct those misrepresentations, in negligent breach of a duty of care which Defendants owed to Pontiac and the Class arising on *Hedley Byrne v Heller* [1964] AC 465 principles, and induced Pontiac and the Class, who were entitled to and did rely on the aforesaid misrepresentations and omissions, to acquire and/or retain Reckitt ordinary shares (or otherwise make investment decisions in relation to those securities) during the Class Period. Pontiac and the Class have suffered loss as a result.

355. In making those material misrepresentations and omissions described herein, Defendants were careless and negligent in imparting the misrepresentations and omissions, had no reasonable grounds for believing the aforesaid representations to be true, or should have known them not to be true. Pontiac and the Class were expected by Defendants to rely on the aforesaid misrepresentations and omissions and Defendants expressed the misrepresentations directly to Pontiac and the Class with the knowledge that the misrepresentations and omissions would be relied and acted upon by Pontiac and the Class. By virtue of the aforesaid matters, Plaintiffs contend that Defendants assumed responsibility to Pontiac and the Class for the accuracy and completeness of the information set out herein. Defendants negligently breached the duty of care

that was owed by Defendants to Pontiac and the Class and induced them to purchase Reckitt ordinary shares during the Class Period and/or to maintain their investment in Reckitt ordinary shares during the Class Period.

356. In reasonable detrimental reliance upon the aforesaid material negligent misrepresentations and omissions, Pontiac and the Class purchased Reckitt ordinary shares and/or maintained their Reckitt investments during the Class Period. But for the misrepresentations and omissions made by Defendants, Pontiac and the Class would not have purchased and/or continued holding Reckitt ordinary shares during the Class Period. Defendants, in the course of their business, profession, or employment, and/or in transactions with Pontiac and the Class, supplied materially false and misleading information and guidance to Pontiac and the Class in connection with their transactions in Reckitt ordinary shares during the Class Period. Pontiac and the Class justifiably relied upon the information. Defendants failed to exercise reasonable care or competence in obtaining or communicating said information to Pontiac and the Class in breach of duty.

357. Because of the aforesaid negligent misrepresentations and omissions made by Defendants during the Class Period, Pontiac and the Class are entitled to rescission of their initial investments in Reckitt ordinary shares and restitution of their initial investment in Reckitt ordinary shares, plus damages as they are determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment as follows:

A. Determining that this action is a proper class action, certifying Plaintiffs as Class Representatives under Rule 23 of the Federal Rules of Civil Procedure, and appointing Lead Counsel as Class counsel;

B. Awarding compensatory damages in favor of Plaintiffs and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Awarding Plaintiffs and other members of the Class such other and further relief as the Court may deem just and proper.

JURY DEMAND

Plaintiffs hereby demand a trial by jury.

DATED: March 26, 2021

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CERTIFICATE OF SERVICE

I, Samuel H. Rudman, hereby certify that on March 26, 2021, I authorized a true and correct copy of the foregoing document to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such public filing to all counsel registered to receive such notice.

/s/ Samuel H. Rudman

SAMUEL H. RUDMAN